UNITED STATES OF AMERICA

ARMED FORCES EPIDEMIOLOGICAL BOARD

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MEETING

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TUESDAY

SEPTEMBER 18, 2001

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The Board met at 7:30 a.m. in the Conference Room of the Armed Forces Radiobiology Research Institute located at 8901 Wisconsin Avenue, Bethesda, Maryland, Dr. Stephen Ostroff, Acting President, presiding.

PRESENT:

STEPHEN M. OSTROFF, M.D., M.P.H., Acting President
DAVID ATKINS, M.D.
S. WILLIAM BERG, II, M.D., M.P.H.
DOUGLAS CAMPBELL, M.D.
PIERCE GARDNER, M.D.
L. JULIAN HAYWOOD, M.D.
JOHN HERBOLD, D.V.M.
PHILIP J. LANDRIGAN, M.D., M.Sc.
KEVIN M. PATRICK, M.D.
DENNIS F. SHANAHAN, M.D.
ROBERT E. SHOPE, M.D.

LTC. RICK RIDDLE, USAF
AFEB Executive Secretary

JEAN P. WARD
AFEB Staff Assistant

PRESENT: (CONT.)

PREVENTIVE MEDICINE OFFICERS:

COL. DANA BRADSHAW, USAF, MC
COL. BENEDICT M. DINIEGA, MC, USA
LTC. MAUREEN FENSOM, CFMS
CDR. SHARON LUDWIG, USPHS
CAPT. KENNETH W. SCHOR, MC, USN
CAPT. ALAN JEFF YUND, MC, USN

FLAG STAFF OFFICERS:

GEN (Ret) ROBERT G. CLAYPOOL
RADM (Sel) STEVEN HART, MC, USN
RADM (Sel) ROBERT HUFSTADER
LTG JAMES PEAKE

ALSO PRESENT:

LARRY ANDERSON, M.D.
LTC. ARTHUR BAKER
CAPT. BRUCE BOHNKER, MC, USN (FSS)
SALVATORE M. CIRONE, M.D.
MR. CHARLIE CRISS
COL. ROBERT DRISCOLL, USAR, MS
COL. ROBERT ENG
JOEL GAYDOS, M.D.
COL. JEFFREY D. GUNZENHAUSER, M.D.
COL. MARK RUBERTONE
CDR. (Sel) MARGARET RYAN
THOMAS SEED, M.D.
COL. MICHAEL STAUNTON
JAMES A. ZIMBLE, M.D.

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C-O-N-T-E-N-T-S

C-O-N-T-E-N-T-S (Continued)

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P-R-O-C-E-E-D-I-N-G-S

(7:38 a.m.)

DR. OSTROFF: Let me start by saying that it's a great honor to be rapping the gavel in place of Dr. LaForce, and speaking for myself and, I think, all of the Board members, we will very sorely miss Dr. LaForce.

Let me call the meeting to order. We have a very, very, very busy agenda, and given the events of the past week, some of the members that we would have anticipated that would have been here are not here. That includes Dr. Carol Runyon, Dr. Elizabeth Barrett-Connor, Dr. Kevin Patrick, Dr. Linda Alexander, and Dr. Moore. And hopefully they will be able to work with us over the coming months.

I applaud both the AFEB Executive Secretary, as well as the Army Surgeon General's Office for carrying forth with this meeting, and I certainly want to thank all of the Board members who have made it here despite the events of the past week.

I think from our perspective that it shows our very strong solidarity with the military both in terms of the terrible atrocities of the past week, as well as what's likely to unfold over the coming months.

And speaking only for myself, but I'm sure for all of the Board members, we request that in any way, shape or form that you need our assistance over the coming months, that we are only too happy to do it. All you need to do is ask.

Before beginning the meeting, as a result of the events that happened last week, I'd like to start by having a moment of silence for those who lost their lives last week not only at the Pentagon, but also in New York City and Pennsylvania.

(Pause in proceedings.)

DR. OSTROFF: Thank you.

Let me also thank Colonel Eng and the staff at the Armed Forces Radiobiology Research Institute. It's a wonderful facility for hosting this particular meeting. We didn't have that much difficulty getting into the complex, not as much as I would have anticipated, and is Colonel Eng --

COL. ENG: Right here.

DR. OSTROFF: Let me present you with this plaque in recognition of hosting this particular meeting, and for those who can't see it, it says, "To the Command and staff of the Armed Forces Radiobiology Research Institute, in appreciation for hosting the fall 2001 meeting of the Armed Forces Epidemiologic

Board."

COL. ENG: Well, thank you very much.

(Applause.)

DR. OSTROFF: Let me also thank Dr. Lofts and Mr. Morse for coordinating all of the meeting arrangements. We certainly appreciate it.

As you're aware, again, getting back to Dr. LaForce, he recently accepted a position as Director of the WHO PATH Meningitis Vaccine Program. This is a very important position. Mark is extraordinarily dedicated to this particular issue. He and I have met about this, and taking that position requires him to relocate to Geneva, and based on the fact that he has to move to Geneva, he felt that the most appropriate thing to do was to resign as President of the Board, and we certainly understand that.

One of the current things that's happening is as a result of the outbreak of meningococcal disease that the pilgrimage to Mecca in 2000, which was caused by the w135 strain of meningococcus, as people left the haj and went to different parts of the world, they disseminated that strain, and it has basically caused a change in the serotype distribution of meningococcal disease.

And one of the major things that's currently being discussed is whether, particularly with the new meningococcal conjugate vaccines that are under development, whether to work harder to include a w135 component into the conjugate vaccine.

And WHO is actually holding a meeting right now to discuss that very issue, and since Mark is going to be the one that is going to carry forth that program, he felt it was imperative that he be there. And we certainly wish him well in his endeavors.

I think that he is hoping that at a future Board meeting that he will be able to keep us informed of what his activities are. We'll miss his leadership and friendship, and hopefully he'll continue to work with us.

Mark was the one that asked that I chair this particular meeting, and again, as I say, I felt it was a privilege to do so.

What I'd like to do before we get started is let me just, since there are many people here, let me have the Board members go around and introduce themselves, if they would. We'll start on this side.

LT. COL. FENSOM: I'm Maureen Fensom. I'm the Canadian Medical Liaison Officer.

COL STAUNTON: My name is Michael Staunton, and I'm the British Liaison Officer at the Office of the Surgeon General from the United Kingdom.

And I would like to this morning just convey my condolences to all of you regarding this tragedy and to say that we also share in the tragedy, and that, indeed, later today I will be making my way to New York to deal with the families of the many casualties we've also shared in this tragedy.

DR. OSTROFF: Thank you.

COL. GUNZENHAUSER: Good morning. I'm Jeff Gunzenhauser, the Preventive Medicine Staff Officer at the Army Surgeon General's Office. I'm the Army representative.

DR. DINIEGA: Ben Diniega, Health Affairs Liaison Officer to the Board.

DR. CAMPBELL: I'm Doug Campbell from North Carolina.

DR. BERG: Bill Berg from the Hampton Health Department. And before I put on this suit, I spent 24 years in the Navy.

DR. HAYWOOD: Julian Haywood, University of Southern California, Los Angeles.

DR. SHOPE: I'm Bob Shope from the University of Texas Medical Branch at Galveston, and

Center for Tropical Diseases.

COL. DRISCOLL: I'm Bob Driscoll, the Designated Federal Official.

LT. COL. RIDDLE: Lieutenant Colonel Riddle. I'm the Executive Secretary for the Armed Forced Epi. Board.

DR. OSTROFF: And Steve Ostroff, and I'm with the National Center for Infectious Diseases at the Centers for Disease Control and Prevention.

RADM. HUFSTADER: Bob Hufstader, the Medical Officer of the Marine Corps.

RADM. HART: Steve Hart, the Assistant Chief for Operational Medicine and Fleet Support, and my responsibilities include support of Navy medicine, research and development, and its preventive medicines and fleet programs.

GEN. CLAYPOOL: I'm Bob Claypool. I'm the Executive Director of the Military and Veterans Health Coordinating Board. I'm not a member of this Board. In a prior life, I had Colonel Driscoll's job and I was a Designated Federal Representative.

DR. LANDRIGAN: Phil Landrigan from the Mt. Sinai School of Medicine in New York City.

DR. HERBOLD: John Herbold, University of Texas, School of Public Health.

DR. SHANAHAN: Dennis Shanahan from Carlsbad, California.

COL. BRADSHAW: Yeah, I'm Dana Bradshaw. I'm the Air Force representative to the AFEB.

CAPT. SCHOR: Ken Schor. I work with Admiral Hufstader at Headquarters, Marine Corps.

CAPT. YUND: My name is Jeff Yund, and I'm the Navy Liaison Officer to the AFEB.

CDR. LUDWIG: I'm Sharon Ludwig, and I'm the Coast Guard Liaison and the Coast Guard Preventive Medicine Officer.

DR. OSTROFF: Thank you.

We have a large number of distinguished guests that are attending the Board meeting. Not all of them are here yet. They will be, I'm sure, in and out based on the situation.

Lieutenant General Peake will be here later on this morning.

I'd like to acknowledge Rear Admiral Robert Hufstader, the Medical Officer of the Marine Corps. Thank you for attending the meeting.

Admiral Hart, who is the Director of MED02, the Bureau of Medicine and Surgery.

ADM. HART: I have a lot of titles.

(Laughter.)

DR. OSTROFF: Admiral Zimble, President of the Uniform Services University of the Health Sciences.

LT. COL. RIDDLE: Yeah, he'll be here later.

DR. OSTROFF: Will be here later.

Colonel Driscoll, thank you once again.

And Major General (Retired) Robert Claypool, thank you once again.

LT. COL. RIDDLE: I have just a few administrative remarks before we begin the meeting today. And I certainly want to thank Colonel Eng and his staff< Rich Lofts and Mr. Dave Morse for assisting and making this meeting happen, and especially for the Board members, to go through the trials and tribulations of the last week and to make the effort to get to the meeting today.

I also want to thank Ms. Jean Ward and Lisa Mims for all of their efforts in supporting the AFEB in preparations for this meeting.

Colonel Robert Driscoll is the Designated Federal Official for today's meeting of the AFEB.

If you haven't, please make sure that you sign in at the registration desk, and for those interested in the tour this evening, we have a sign-in

sheet out there, and you know, a lot of people aren't aware that, you know, you're in a lead shielded building sitting on top of a nuclear reactor. We couldn't think of a safer place to have the meeting.

(Laughter.)

LT. COL. RIDDLE: But there will be a tour of the facility this evening, and if you're interested, please sign up.

DR. OSTROFF: And is it true cell phones don't work inside the building?

LT. COL. RIDDLE: I couldn't get mine to work inside the building. Yeah, so I think it's because of the lead shielding, is what they told me, yeah.

So we'll have refreshments, buffets, morning and afternoon. Lunch both days will be on your own. The cafeteria over at the Uniformed Services University; they have a McDonald's and some other fast food over at the Naval Medical Center, and then certainly Restaurants in the local area.

Restrooms are just right outside the conference room. There are three telephones that have been set up in the break area, and you just have to dial 99 for an outside access or 991 for long distance.

If you have any fax copies or messages, just see Lisa at the registration desk.

And then we have subcommittee meetings this afternoon and tomorrow, along with the executive session, and what we'll do is we'll try to meet here and maybe break out in groups here or use the break room or another facility to get those meetings done.

Tomorrow's executive session will be here. Certainly for the speakers, we do have a robust agenda, and we'll have to be flexible. When General Peake comes in, he wanted about 30 or 45 minutes to address the Board, and certainly when he gets here, we'll just break with the schedule and give him that time.

Also, remember that this is a federal advisory committee. You are being recorded and transcribed. So please identify yourself when you speak, and we have microphones set up for the audience and then here at the table.

For dinner tonight we'll meet at the lobby at the Hyatt at around 6:30, and we have reservations over at the Rock Bottom Brewery.

Also, certainly members of the public and press may be in and out today. So be aware of that with your remarks.

DR. OSTROFF: That's it?

LT. COL. RIDDLE: Yes.

DR. OSTROFF: Thank you.

Why don't we turn the podium over to Colonel Eng, who will begin the program by giving us an overview of the Armed Forces Radiobiology Research Institute?

COL. ENG: Well, thank you very much. I appreciate the opportunity to host the AFEB meeting.

You already have a copy of my presentation in the binder before you, but let me give you a copy in color, and it may clarify the graphs, which the color would better indicate. So let me just hand it out to the rest of the group in front. So you have a black and white in your three-ring binder at this time.

It's my great pleasure to offer AFRRI to host this meeting. Colonel Riddle and I were talking, and we don't believe that you've ever held a meeting here at AFRRI before.

One of the things that I want to really point out is the fact that AFRRI, the Armed Forces Radiobiology Research Institute, is really your institute. Our mission is medical readiness, and that's we're all about, to service not only DOD, but

our nation, and I will go through a little bit more about that as we get into our briefing.

One of the things that I do want to mention is the fact that we've been here. AFRRI got started back in 1962 during the Cold War era, and the facilities that we have was geared towards research to look at the data that was required to deal with the Cold War issues, but has since transitioned into today's environment on how to deal with the radiation injuries and the challenges we all face, whether it be the challenges on a nuclear radiological battlefield, to that of domestic issues and WMD issues that we face.

I can say right now that we are engaged significantly.

These are some of the things that I want to highlight, and there are some misperceptions. The fact that there are effective drugs to address the radiation induced injuries that appear; the challenges that we have is nothing new to us because during the Gulf War, Desert Shield, the AFEB was engaged in looking at FDA approved medications or IND medications, and these were very efficacious.

But because of the potential off-label use or IND status, we had certain challenges with the FDA

regulation.

We had the same situation here in terms of these effective drugs. We're talking about cytokines, the Interleukin-11, and the granulocyte colony stimulating factor that are FDA approved, and they are efficacious for radiation induced injuries, but that is not an indication.

And so I believe that that is one of the discussions in this meeting these next two days.

One of the misperceptions is the fact that we have a lot of the information already to address the radiation induced sepsis as caused by the irradiation, as the data that has come out of cancer therapy. That is far from the truth. In talking with Commander Douglas, the Chief of Radiation Oncology over at the National Naval Medical Center and auto oncologist (phonetic), they don't get into a problem like that.

They have fractionated exposure. You won't see the type of injuries that we will see in a battlefield or in a radiological or nuclear event. So they don't get into a situation where the crypt cells and the lining of the intestinal walls are destroyed because they do not want such complications because it would complicate their treatment.

And so there is a void, and so a lot of that information has to be generated, and we're focusing on that as one of our new projects.

The fact is antibiotic treatment and all of that, the resistancy that is occurring in a dynamic mode is causing a lot of challenges, and if you look at the various places where our troops are going to deploy, the organisms that are increasingly resistent to antibiotics will pose a challenge to all of us.

This is the briefing outline. When we talk about the threat, the threat situation goes from a worst case scenario, low probability, high liability, all the way to increasing probability and lower liability, all the way to a situation where from the battlefield we get into involvement with CONUS and terrorism in a nuclear radiological sense.

In terms of the specific threats, we're looking at the radiological dispersal device where you take a large radiation source, whether it be an industrial source or a medical source and place a large explosive device on it and detonate it in a situation of opportunity, highly traversed area, heavily populated area.

The issue there is not only the injuries that will occur, but also what we call the

radiophobia, the "worried well" based upon the experiences not only in World War I, but with the Tokaimura criticality accident, and many other incidents.

One of the issues and challenges we face from a medical perspective are the "walking well" or the "worried well," and those are the individuals that may flood our medical system, and so when we have a challenge discriminating and differentiating those who are actually injured and actually need medical attention versus those who really believe, really believe that they are injured, but do not need attention, but they need the reassurance and the psychological countermeasures or to be addressed in terms of their mental health status.

In terms of placement of radiation sources, a scenario that we're very concerned about is the fact that parties to be, groups may place multiple sources throughout the United States in highly traveled areas, subway systems, and then two months afterwards, then they identified the location of the sources.

Individuals may or may not have symptoms, and then they say, "Oh, my gosh, I've been at these subway stops," or, "I've been at these locations that

were identified by the terrorists, and I don't feel so good."

But the terrorists identified the location of one of the sources and said, "We have many other sources elsewhere," and can you imagine the phobia? Can you imagine from the medical systems, the medical personnel that would have to address this situation?

It would be just a tremendous challenge to all of us to deal with such a situation.

Certainly one of the considerations that we have is the construction of nuclear reactors in the area of operation, and we're principally looking at the old CONUS situation in the various theater of operations, and that's what we're trying to engage.

I'll show you a map of some of the reactors that we're concerned about later on, and certainly the use of nuclear weapons, maybe not sophisticated, what we call improvised devices, certainly not at the efficiency of the technology that we have, but improvise, it could be very effective in producing KT type yields, kiloton yields.

Our mission is medical readiness, and the components of that medical readiness is to do research, and the research is to develop products to prevent, assess, and to treat the radiation

casualties, the injuries, also to develop techniques or procedures to give to health care providers on possible best ways to treat individuals.

Certainly we train medical personnel with the medical effects of ionizing radiation course. Before last Tuesday, we have a group over in Asia, in Japan, and they were still in place, providing training to U.S. medical personnel in Japan and Okinawa.

Right now we still have them in place, and they're scheduled to move out to Korea to provide that training. It's the first opportunity we have to train not only U.S. personnel, but also the Korean military and civilian medical personnel.

So they were in place, but I have a very short leash on them. In case something happens, I will pull them back. I will not hesitate to do that.

In terms of advice, we have a memorandum of agreement with the J-4 medical, as well as OSD, Nuclear Matters, as well as our commitment to the CINCs, CINC surgeons, and other individuals. In fact, we were called by one of the CINC surgeons asking for support. I deployed one of my officers yesterday.

Certainly we have a team, and I'll say a little bit more about that team later on.

We have sources, as Colonel Riddle mentioned, and Dr. Ostroff mentioned. We have some sources which very few people know about. We don't advertise it because to us it's the normal operations. Okay?

The first source we have is our trigger reactor. We can simulate the nuclear pulse of a detonation or go continuous mode irradiation.

One of the things is we do not have a power reactor. There is not an opportunity for a criticality event. The way that the trigger reactors were built and designed is the fact that it isn't possible for it to go critical because once it achieves a certain temperature, it has a self-quenching mechanism that shuts the reactor down.

And so there's absolutely no way that it can go critical mainly because of the design of this type of research reactor. It is a very unique reactor because of our two exposure rooms, and for those taking the tour, you'll see.

Those taking the tour, we'll pulse the reactor, simulate the radiation pulse from a detonation, tremendous shooting from the water so that you'll get zero dose. Okay?

You'll see the Cherenkov radiation, which

is exactly what the Japanese, the three Japanese individuals saw at Tokaimura criticality event without the dose. So you're see the Cherenkov for those taking the tour.

We also have a high level cobalt radiation facility rated at 400,000 Curies, and so we can do any experiments that we need or investigators.

Indeed, we have a linear accelerator that can give us a 54 MeV electron, giving us a good dose rate on X-rays. We also have a low level exposure facility to look at very low level chronic exposure, which is an issue that the folks in Europe encountered and something that is an issue to all of us.

We have a veterinary facility, which is a 35,000 square foot facility. We house rodents up to procines, canines, non-human primates.

In terms of a research team, we have four research teams, and I'll say a little bit more about each of these teams.

In terms of the first team, Dr. Seed, the requirement there or the objective there is to look at the development of products of drugs, pharmaceuticals to reduce the number and severity of the radiation induced casualties.

We're looking at pre-treatments and

treatment drugs, and the philosophy is the fact that if we know that our folks are going into harm's way, into a nuclear environment, a radiological situation, the pre-treatments may be used to minimize the potential exposure, and if this happens, and even though they're exposed, at least the injury is minimized, and so you have a greater opportunity to deal with the injury because it would not be as severe.

And so an ounce of prevention is worth a pound of cure, and if, indeed, they don't have the pre-treatment on board, we're really working heavily on the treatment modality, looking at restimulating the hematopoietic system.

Indeed, one of the products that Dr. Seed and his group are looking at is this particular steroid, the 5-Androstenediol. We're talking about providing the steroid one day before the exposure to two and a half grays (phonetic) in the rodent model, and we're looking at subcu. administration versus oral.

If you take a look at the controlled group, no medical intervention with the irradiation. Get about 20 percent survival approximately, 15 to 20 percent survival.

But if you provide the medication in an oral fashion one day before, you get about 50 percent survival. But then if you give it subcu., you're looking at potentially 100 percent survival.

This is quite an amazing compound because if given even two hours after exposure, you get the same results. So not only is it a potential pre-treatment. There's a potential -- and I only say "potential" -- that it might be even a treatment modality.

In terms of biodosimetry, we're talking about a situation where a lot of our troops are maybe in a domestic situation. A lot of our folks may not have the physical dosimeters that a lot of us carry. Okay? Not the thermoluminescent detectors.

In the military, in the Army, we have the DT-236, but it's very difficult to imagine that a lot of civilians are walking around with their dosimeters. Okay? And so we have to have a way of estimating the radiation dose to allow for triage potentially and/or assessment of the unit radiological status.

Certainly in this particular situation, one thing is to draw the blood and make an assessment. The current gold standard procedure takes about three days, two and a half to three days, an unacceptable

length of time.

We've shortened that to one day, but our objective is to develop an assay that would be able to be performed in less than an hour or even shorter.

AFRRI is the only DOD lab with such capabilities, and one good thing is that this lab capability is a reach-back capability for a deployment team, and so our institute is there to support our deployment team.

We take a look at the possibility in terms of where that biodosimetry capability can be infused or incorporated into the battlefield. We know doggone well that the battlefield will become asymmetrical very quickly in the future. So it's not going to be a nice, neat, orderly arrangement, and there's going to be significant challenges for all of us.

So this is the best case. Asymmetrical is probably the real situation where there is not straight, nice line of delineation on the battlefield.

In terms of the NBC interactions and countermeasures, what we're talking about is the combined insult and synergy effects of not only radiation, but also something else, whether it be chem. or a bio. agent.

We're refocusing this study into a

different area, and that is the translocation of the normal gut flora, the enteric organisms as far as a translocation as induced by radiation. That's what we're refocusing this effort.

But I just want to show you a little data in terms of what we found in terms of the combined injuries of radiation and a Bacillus anthracis Sterne insult species.

So this is what we're transitioning to, and certainly all of the data allows for incorporation into a casualty model.

This is an example of the results that we have during the combined injury studies. If we take a look at the rodent model and seven grays (phonetic) of exposure, 100 percent survival. But if we provide an intratracheal infusion of the Bacillus anthracis Sterne with that quantity, we get about 60 percent survival.

If we combine both the radiation and the Sterne insult or Bacillus anthracis Sterne insult, we get less than a percent survival, and that's the example of combined injuries.

But what happens if we were able to pre-vaccinate the rodent and then provide the insult or insult the animals with the Bacillus anthracis alone?

As seen with the vaccine that a number of us have been vaccinated with, we get 100 percent survival, just as we would expect. But, indeed, if we put not only vaccinate, but also irradiate the rodent model, we don't get 100 percent survival. We get 80 percent. We still get 20 percent mortality, and this is unacceptable to us.

And so we have to find ways to reduce this mortality rate, and that's one of our objectives.

One of the other things is the fact that when we talk about combined injuries, there's a lot of information we don't know, and this was a surprising finding to us at least. We talk about the combined injuries of radiation and also the Bacillus anthracis, but we also are looking at the bacteria that's isolated from the various organs and tissues of the mice to see what organisms profuse and/or challenges to infection and what we may have to do for those radiation injured casualties, service members.

If we just take a look at just the irradiation alone, and we're talking about sub-lethal irradiation in the various doses without a challenge, we find that the organisms as isolated from the various organs and tissues of the rodent -- there are none. That means the gut is intact. The crypt cells

have not been destroyed. The lining is intact, and so that prevents the translocation causing sepsis.

If, indeed, we just provide the spore challenge without the irradiation, just the spore challenge, what we see is the fact that, indeed, as you would see, we have the Bacillus anthracis, the Sterne species, isolated from each of the organs and the various tissue as expected during a challenge of the Bacillus anthracis.

But what happens when you combine both a sub-lethal irradiation and the spore challenge? What happens here at the various three, five, and seven gray exposure with a spore challenge, we see not only the Bacillus anthracis, but we see all of these other organisms that have translocated.

We didn't expect to see that. We anticipated that if, indeed, there was no synergism, we would only see the Bacillus anthracis just like up here with a sub-lethal exposure. But we have all of these other bacteria which ciprofloxacin by itself would be inadequate to treat these individuals.

And, again, throwing in the resistancy to the various antibiotics, we do have challenges, and now with this data we alert the health care providers that they may have challenges if we ever get into a

situation like this.

So this is the type of data that we're generating.

Certainly you have heard about the challenges in the depleted uranium arena where a number of our soldiers have come back from Desert Shield and Desert Storm, and there's implications of potential health effects.

Note that the numbers of individuals are very low from a statistical point of view, and to date we have not found or the VA has not elucidated any definitive ill health effects. We are doing studies in that arena to look at potential carcinogenic and mutagenic effects, and that's the studies that are ongoing here at AFRRI, and AFRRI is the only DOD lab performing that type of study. And we were very instrumental in providing the open literature, peer reviewed journals or peer reviewed articles on that, providing it to our NATO allies and all the so-called individuals very concerned about this.

So we're trying to play the honest broker on that.

This is one study we've done looking at the human osteoplast sarcoma and looking at the transformation of that particular cell line when

exposed to depleted uranium and a number of other potential metals that are known as carcinogens, mutagens.

And what we're looking at here is the transformation rate when these cells, the osteoplast sarcoma, the normal and the transformed; when they're exposed to the various metals. And this gives the rate of transformation per 500,000 surviving cells.

Then on this line we're taking a look at the number of tumors formed when a million of these transformed cells are injected into immune compromised rodent. As you can see, with the insolubility yield, you get a tremendous transformation rate as opposed to the controls.

But the tungsten, nickel, cobalt is considered as a potential replacement discussion. But if you look at this potential replacement, it may not be as free from concerns.

And so if, indeed, there is considerations, we really have to take a look at it, and you can see the potential tumorigenicity issues here, too.

But the ace in the hole is the fact that phenyl acetate could possibly mitigate these effects if, indeed, we find that there is a situation there.

And so we're looking at potential ways of dealing with it not only to potentially identify.

I don't think there's any doubt in our minds that next time if we ever get into a tank-on-tank battle, that we are not going to be the only ones with a DU, and so we are not just going to see friendly fire casualties in terms of DU casualty, but they will be OP-4 inflicted.

Operational support in terms of the course itself, I mentioned the fact that our team is in Asia right now. We provide a lot of training throughout the year, but of course, in DOD, as you all can imagine, the budget situation is really a challenge, and we've been told that our budget will be potentially zeroed out next year in FY '02 on the training aspect, and so that poses challenges for us in terms of having to look at the potential of distance learning.

But, indeed, that is a challenge not only for us, but also for the medical management chem.-bio. casualty course also. So we all face challenges in these austere times.

In terms of our advisory team, this is our team that deploys. This we deploy as part of the consequence management advisory team, which is the DOD

team that deploys to a weapons incidence, Broken Arrow situation, a radiological emergency.

We stood up and are on alert as of last Tuesday, and we're prepared to deal with any situation.

Today I was supposed to travel to Japan right after this talk, and so face the challenges of Dulles airport, but I've decided that it's prudent that Colonel Jay Cox and myself will not go and let the folks that are over there deal with it, and so we're in place to deal with any situation, and hopefully we will not have to do that at all.

But these are the things that we have the capability of doing with our team.

Our concern is in the Korean theater, the number of reactors there, locations. We've developed plumes and plots, and there are certain situations that we're very concerned about in terms of the release of the radioactive components in the core if there is an incident, if there is a conflict on the peninsula.

The same type of challenges in Japan not only from the operatives, North Korean operatives in Japan, but also the situation that Japan is earthquake prone, and if you look at most of the reactors,

they're along the coast for cooling purposes. But if there is a severe earthquake, not only the direct effects of the earthquake, but also the tsunami that could be generated on that.

In the '20s, there was an earthquake called the Great Continental Plain earthquake. At that time, that was before the Richter scale was developed, and at that time, although there was only a description of the magnitude of the destruction, it was postulated that the Richter scale assignment was either in the eights or high eights, which is quite dramatic because that's a log factor scale.

In conclusion, the readiness aspect is a now situation rather than a later situation. We've always stated that it's better to develop a plan now rather than to develop plans or contingency plans during a crisis because that is the worst time to develop a plan.

It's always nice to pull a plan off the shelf and spruce it up and modify than to have to go into a crisis mode because we'll have a thousand things on our plate, and it is not the optimal situation.

So that concludes my briefing. Again, I certainly am gratified to host the AFEB meeting here,

and if there's any situation or issues or needs, please let me know or my folks know, and I'm sure that a lot of the topics on the agenda are of tremendous interest to us.

And, again, thank you very much, and subject to your questions, that concludes my briefing.

DR. OSTROFF: Thank you very much, Colonel Eng.

We have just a couple of minutes before we get into the preventive medicine updates for questions. I have a couple that came to mind.

One of them is I wonder if you could speak to what type of staff you have in a facility like this. Most of us are primarily in the medical arena, but I would imagine dealing with the types of things that you deal with that you also need to have nuclear physicists and personnel such as that. I wonder how you staff the facility in terms of very specific areas of expertise.

And the other question that I had was when you're talking about trying to determine or develop rapid detection methods to determine if someone has been exposed to or had a nuclear exposure, is anybody thinking about noninvasive ways to be able to make that determination?

COL. ENG: Let me answer the question on the staffing. I have the commitment from the services, Army, Navy, Air Force, staffing from the military perspective, officers and enlisted, have approximately 160, 170 individuals, military and civilian, approximately half and half in terms of military and civilian.

The type of specialties that I have range anywhere from support staff or logistician to health physicist, to biochemists, microbiologists to physicians. I have physicians and health physicists on my response team, but they also serve other functions in terms of the training, the medical effects of ionizing radiation course, as well as occupational safety, occupational safety physician.

And so we do a lot of double dutying and a lot of overlapping responsibilities. So Army is the largest number. Navy comes next, then Air Force. You see a varied diversity in the science area to approach all of these functions.

In terms of the second question was?

DR. OSTROFF: Noninvasive mechanisms to identify whether someone has been exposed.

COL. ENG: Actually the mechanisms we were looking at are to draw blood and to take a look at the

potential chromosome damage in the blood, and that's sort of the gold standard in looking at the dicentrics and centric appearances during a specific dose of radiation, therefore a correlation to the estimated radiation dose.

One of the things we're getting into that we think may give us tremendous sensitivity is to look at bioindicators, molecular indicators that may be more sensitive to give us an estimation.

Again, it would require the sampling of withdrawing blood samples. Right now there are some studies being done to look at the electron span resonance signals in terms of a noninvasive, maybe nonsampling of bone type tissue, teeth or whatnot, invasive and noninvasive to look at that.

But we were looking at at least the sampling of blood and looking at the sensitivity of that at this time. We think there's tremendous opportunities there, and there is an international panel, ISO panel, taking a look at the standards of biodosimetry from an international perspective and to see what studies or techniques can be adopted on the world. So that's what's happening.

DR. OSTROFF: I mean, I would think with the DARPA folks, they would just figure out some way

to just wave a wand over somebody eventually or something like that and tell whether or not they've been exposed.

There are a number of other questions. Let me start with Phil.

DR. LANDRIGAN: Colonel, I've got two questions, please about the 5-Androstenediol. First of all, you said that it would still be effective two hours after an exposure, and I wondered if you were pushing that envelope to see if you could get out beyond two.

And then my second question was I wanted to ask if you had plugged that compound into those synergy experiments that you describe where you expose the animals simultaneously to radiation and to the various bacteria.

COL. ENG: On the second question, that would be the ideal situation. We have not performed those studies yet. That would be ideal to include some of the other pre-treatments that we currently have that show promise.

Is Dr. Seed in the audience?

Dr. Seed can address your first question.

Could you go to the microphone, Dr. Seed?

DR. SEED: Concerning the second question,

actually we've done some experiments with combined injuries and the protection with 5-Androstenediol against the infectious challenge within irradiated animals, and it's quite effective there.

On the second question, the second question was?

DR. LANDRIGAN: Could you push out the envelope? The colonel had mentioned that it was still effective at reducing casualties if you administered it two hours after exposure, but can you push that out to three, four, six, 12?

DR. SEED: Those experiments haven't been done yet, but we do know that shortly thereafter irradiations, in contrast to some of the more classical radioprotectors, this protects after the exposure.

DR. OSTROFF: Yes.

GEN. CLAYPOOL: You know, terrorists seem to go after relatively soft targets or unexpected targets, and in the nation these days, it seems that chemical and biologic weapons of terrorism have garnered a great deal of public interest and support.

I'm a little concerned that as a nation maybe we're not focusing as much as we should on trying to be able to either prevent or deal with the

medical consequences of some sort of a radiologic terrorism.

I'm just curious. Are you aware at the national level is there some agency like Department of Energy that has the lead on looking at this? And if so, is Department of Defense participating with this in terms of looking out over the horizon to try to reduce the risks and be able to address any of the consequences?

COL. ENG: As you know, the legislation is concentrating mainly on the chem. and bio., and for the response teams. Early on we tried to interject to surgeons, the National Guard NGB surgeon, in terms of trying to incorporate and include the radiological training.

And indeed, because of the restriction of the legislation to address only chem. and bio., there were hands tied such that they did not get a robust training in the radiological area, and so there has been some shortfalls in that training, and so the emphasis has mainly been on chem.-bio., and we are behind in terms of that radiological readiness.

So I don't have a good feeling. I really don't feel very good about that because of that, of what's happening.

DR. OSTROFF: Colonel Bradshaw.

COL. BRADSHAW: Yeah, Colonel Eng, I just wanted to ask if, and confirm, I guess, that when you're talking about the biodosimetry measurements that you're speaking of whole blood and not serum.

And I also wondered if you had looked at this in stored blood. Can you still do the same kind of measurements?

COL. ENG: I'm going to have to defer to Dr. Blakely. I know that what we're really keying in on in terms of the dicentric and the centrics are the white blood cells. That's the component we're looking at in terms of the chromosomal defects for an estimation of the radiation dose.

When we start taking a look at the molecular indicators, we're looking at the components of the plasma.

If Dr. Blakely is here, we'll get an answer, and I'll get you two together for any more definitive response to that.

CAPT. SCHOR: There have been a lot of open press reports about threats to nuclear reactors, power generation plants. Do you have any comments that would be appropriate to discuss that threat in this audience?

COL. ENG: Note that the power reactors -- we've made a number of assessments in terms of the downwind plume and also the construction of the reactors, the so-called Western design with the containment facility versus that of the graphite reactors which do not have a containment facility.

I was able to visit last year the St. Petersburg reactor right outside of St. Petersburg, which is a graphite reactor, and it's really quite an opportunity to stand on top of the core of the reactor and look at all of the fuel rods and the Cherenkov radiation glowing from the fuel rod. It's really interesting to step into the generator room and see this gigawatt generator with a shaft about yea.

The graphite reactors are a situation where we've assessed that if there is a bad situation, which the quality assurance has really been heightened because of Chernoble, a lot of quality assurance even by the Russians have been put in place, but if something should happen or assessments in terms of the threat to U.S. personnel in EUCOM is such that it will not hit the action level that mandate the use of potassium iodide, the activity levels will be above background, but nowhere should it trigger action levels because of the distance and the dilution factor

as it would reach the U.S. population in EUCOM.

It's a little bit different if we take look at the Korean and the Japan situation because of the greater challenges there, but let me just state that there's one situation that would challenge a Western design reactor. The way it's real critical is the fact that there is a primary cooling system as well as a back-up cooling system, and this is in all Western design reactors.

The only way that a criticality can occur is the fact that both systems are simultaneous, and I quote "simultaneously," corrupted. Then we get into a potential criticality because there's not enough cooling capacity to take away the heat load of the core.

If it occurs sequentially, that's usually not a problem because there's enough capacity, but if somehow the OP-4 or operatives are able to disable them simultaneously, we could get into a pretty bad situation, and I think that the OP-4 terrorists know this fact, and it's whether, indeed, there are operatives in those countries.

And certainly if there was a conflict on the peninsula, one of the things you'd want to do is shut those reactors down and really cause us to have

problems, not only the South Korean folks, but ourselves in terms of disruption of activity.

If you look at California, what that did to compromise your abilities to carry on normal operations with your power shortage. So that's what the situation may be.

DR. OSTROFF: We have time for one more question. Dr. Haywood.

DR. HAYWOOD: What's the duration of protection of the vaccine? Duration of protection?

COL. ENG: For the?

DR. HAYWOOD: The vaccine.

COL. ENG: The vaccine. Are you talking about the anthrax vaccine or --

DR. HAYWOOD: No, the Andros-3 (phonetic).

COL. ENG: Duration of protection. I'll defer to Dr. Seed.

DR. SEED: We've gone from 24 hours prior to exposure down to two hours after exposure. So, again, the window of protection is between 24 hours, again, prior to exposure all the way through just following exposure.

DR. OSTROFF: Can I ask one last question?

I was really fascinated by the data you presented about the combination of the radiation

exposure and then the anthrax exposure, and I'm curious because it wasn't clear to me from the presentation. The anthrax exposure, was that an aerosol exposure or was that an oral exposure?

And I'm wondering if you tried it both ways to see if it made a difference since there are various ways that anthrax causes disease.

COL. ENG: The route of exposure for the Bacillus anthracis Sterne species, not the weaponized species, was intratracheal, and the reason why we went with the intratracheal and the Sterne species is the fact that that allows us to conduct the studies here.

We had plans to conduct the inhalation experiment with the weaponized Bacillus anthracis, but unfortunately, the focus of our study as mandated to us was to stop that study and focus ourselves to the translocation of enteric organisms in the gut.

And so those studies have been put on hold by powers above us. So that was something we had planned to do, but because of priorities set upon us, we'll not be able to do that in the near future.

DR. OSTROFF: Well, thank you once again, and once again, thank you for hosting the meeting. I'll look forward to the tour this evening.

COL. ENG: Well, thank you very much.

DR. OSTROFF: Why don't we move on to the updates? I think the first one is from an old friend to the board, Colonel Diniega.

DR. DINIEGA: Am I that old? I hope you didn't mean chronologically, Steve.

DR. OSTROFF: Huh-un.

DR. DINIEGA: Good morning, and I'm always glad to be a part of the Board activities.

What I'd like to do is just provide a little bit of an update on things that have occurred since our last meeting.

Next slide.

This is the agenda that I'd like to address this morning. These are issues that are at least high up on our plates and our radar screen at this point.

The influenza vaccination policy, because of the slow-down in distribution, was signed on September 10th by Dr. Clinton. We average about three million doses a year, and we had a sole source producer this year in Aventis Pasteur.

Our delivery schedule, as with the rest of the country, has been slowed down, but we're a lot better than last year. We expect 25 percent by mid-September, 65 percent in October, and the remainder by

the beginning of November.

At this time last year, by mid-September I think we had about 250 doses only.

The priority pretty much follows the last year's scheme, priority to medically high risk patients, operational forces, and direct health care providers. And we've asked that all our facilities delay mass vaccination campaigns until November, after delivery of the remainder of our vaccine.

Tetanus containing vaccines continue to be in short supply. The company, the manufacturer states that this will probably extend into early 2002. In May, and I think it was briefed at the last meeting of the AFEB, there was a consensus statement by the Joint Preventive Medicine Policy Group that was distributed to all of the services.

The priority for vaccination goes to people traveling to diphtheria risk countries, to be used for prophylaxis in wound management, and to people and persons with less than three doses of tetanus.

This will be a controversial topic. The IOM is expected to release a report on 20 September, and this is from the Vaccine Safety Committee of the IOM.

The Interagency Vaccine Group, which is a federal agency, and I'm the DOD liaison to the group, is currently preparing a statement on its release, information papers and Q&A sheets to be used by public health departments across the country, and they will share all of those with DOD, and we'll be able to utilize that in our system.

Yellow fever vaccine, I'm sure you've all heard of the seven deaths following vaccination reported in the last MMWR Notice to Readers on 3 August. There were seven deaths between 1996 and 2001, all of multi-organ system failure related to vaccination with the current vaccine.

The JPMPG, we're going to review our service policies, take a look at the CDC recommendations, and we expect more to come out after the ACRT meeting in October and certainly look at the risk information as this is considered one of the safest vaccines around.

The current crisis, just to let you know that we do have a 24-hour emergency operation center, and the Office of the Secretary of Defense Crisis Control Center and the Executive Support Center has been operational sine the afternoon of the tragedy.

We have a Health Affairs Desk that is

manned 24 hours, seven days a week, and it's manned by Colonel Driscoll's shop, Health Operations Policy, and they're doing a great job.

And our primary mission is to coordinate medical issues between the Office of the Secretary of Defense, who decides on medical support to be given outside of DOD and also within DOD, and other agencies and services to include the Joint Staff, the services, FEMA, Office of Emergency Preparedness, et cetera.

Each of these agencies and services had their own 24-hour emergency operation center, and on the schedule you'll see that General Peake, the Army Surgeon General, will be speaking on medical support to current operation later on in the morning.

Subject to your questions, that's my briefing.

DR. OSTROFF: Thank you, Colonel Diniega.

DR. GARDNER: Ben, I was at a meeting in Atlanta last week, actually last Tuesday, dealing with the influenza issues with CDC, and I guess, although it's one of the interesting issues for us to consider, is it looks as if the live, attenuated influenza vaccine will probably be licensed for adults reasonably soon. It's a little less clear what the pediatric age will be.

But, that looks pretty good in terms of protection and mucosal immunity. It may actually have some herd immunity that might be important, particularly in the military situations.

Are there studies or considerations for what we'll do if and when that vaccine becomes available?

DR. DINIEGA: Well, I think we've discussed this at several meetings, and number one is we'll have to wait until it becomes licensed.

Number two, we'll have to take a look at the cost and then take a look at the CDC recommendations and then decide whether or not -- see, we usually follow ACIP recommendations unless there is a military unique reason for our own recommendation within the approval process and within the purview of the approval.

So we would discuss it at the Joint Preventive Medicine Policy Group at least before we would decide on any further recommendations concerning use in the military population.

I think the issue will probably be cost as one of the biggest issues.

DR. OSTROFF: Yes.

DR. BERG: Bill Berg.

Ben, coming back to the tetanus containing vaccines, as I recall, the CDC had a fourth group in the priority listing, women, pregnant women who had not gotten a booster dose for more than ten years.

Did the JPMPG buy into that also, or did --

DR. DINIEGA: I just gave you to top three categories, and I do have a statement there that I can share with you, but that was on the list for prioritization of the vaccine.

DR. BERG: Thank you.

DR. HERBOLD: Ben, you mentioned for the influenza vaccine that one of the priority groups were operational forces. Does that include or exclude training commands, training installations?

DR. DINIEGA: There is a separate group for recruit training. You're talking about recruit training, and I think one of the problems we had last year with the slow-down in distribution, one of our larger concerns was being able to vaccinate prior to Christmas leave, and I think it looks like we'll be able to do that this year, although for the early use of the vaccine, we have not put them up as high as operational forces that we'll need to deploy.

In today's current situation, I think that

even takes on more significance. So we're hoping to vaccine the recruits prior to their going on Christmas leave. That's what we'd like to do.

But operational forces, when we speak of operational forces, it's headed as those that will deploy, and the immediate deploy should have the highest priorities.

Sir.

DR. LANDRIGAN: Phil Landrigan.

Ben, what's your betting on how the IOM is going to come down on thimerosal?

And related to that, is thimerosal really an issue for adults? I thought that was principally a pediatric problem.

DR. DINIEGA: You're exactly right. The issue that CDC and American Academy of Pediatrics have been addressing has been the use of the preservative in vaccines for infants and children, and that is the focus that they have. Although we do know that there are some adults who have problems clearing mercury, I'm not so sure that they're going to answer that.

And then as far as do we know what they're going to say, when I sat on the teleconference the last time, and I don't know if Dana, who substituted for me recently, has any further information, the

issue was going to be still focus on children. And actually the interagency vaccine group was not too sure what was going to come out until they saw the report which they thought they would get advance copies several days ahead of the release.

Dana, do you have any?

COL. BRADSHAW: Yeah, I asked that question specifically about the adults, and it does seem to focus primarily on children.

Just to bring in the perspective on adults though, we have had some Gulf War veterans actually come before chief of staff of the Air Force and also Admiral Clinton in Health Affairs with concerns about the amount of thimerosal and organic mercury that they might have received getting multiple vaccinations, including also immune globulin which had thimerosal in it because of what they get in a single dose, maybe getting as much as 100 micrograms or so at a time.

And the confusion there comes in in how they've interpreted the EPA's referent dose, which amounts for a 70 kilogram man about 17 micrograms, you know, as allowable.

But the referent dose is actually for a lifetime minimum, and they interpret it as a single even though the EPA says that that's not supposed to

be the way that it's interpreted. But again, you're working with lay people and their concerns are of that nature.

DR. OSTROFF: I think -- one more?

COL. STAUNTON: Yes. Michael Staunton, United Kingdom.

I'd like to raise the issue about vaccination with horse (phonetic) protection and preparation, whether or not as part of preparation vaccination is envisaged and what implications you think that might have for a combined -- for something particularly if we're working as allies, that we should seek to use exactly the same vaccinations.

DR. DINIEGA: You're talking about use of vaccine on a multi-national course level. I am familiar with some of the issues mainly because I used to at one time in a previous assignment work on NATO issues, and I know in the arena of biological warfare, the NBC Working Group has a standing subcommittee that is looking at making recommendations and only recommendations. I don't think they're headed towards a STANAG (phonetic) on vaccines to be used in NATO operations.

The issues are many. The issues are licensure, and the issues are procurement issues and

purchase issues.

But I think it would be good to have sort of a standardized approach to it. I know during the Persian Gulf War when I was the Preventive Medicine Officer in Korea, the south Korean Republic of Korea forces did come to us for assistance in procuring vaccines that they knew our U.S. military was being vaccinated with prior to going over to Southwest Asia.

And we did cooperate and assist them, and there has been other instances where that has occurred. I think the nice thing is that in some of the vaccine development arenas it has gone to multinational development.

DR. OSTROFF: Okay. I'm going to try to keep on schedule, but I do have one more question I wonder if you could address.

DR. DINIEGA: Of course.

DR. OSTROFF: Being that we don't have the good Colonel Grabenstein on the schedule this time, the first time in quite a while, I wonder if you can address if there are steps being taken to try to get the other lots of anthrax vaccine that currently haven't been released by the FDA release.

DR. DINIEGA: I think the efforts that he briefed on at our last meeting continues, and the

controversy over the vaccination program continues. I think we're all aware that it's down to a real trickle and selected use of the anthrax vaccine because of the short supply.

DR. DINIEGA: I think it's a much more critical issue now to try to get them released.

COL. BRADSHAW: This is Colonel Bradshaw.

There has been work done on an IND protocol to use other lots of vaccine for post exposure prophylaxis, along with ciprofloxacin. So there is a protocol that some of the lots that may not currently be FDA released, that in such a contingency those lots could be used if you did know of an exposure.

The other thing is I was in a meeting just yesterday, and particularly the events of the last week, there's been some plus-ups in money, including additional monies to try and get an additional fermenter at Bioport to try and increase their capacity.

DR. OSTROFF: Thank you.

Let's move on to Colonel -- and I'm bad with names -- Gunzenhauser.

COL. GUNZENHAUSER: That's good.

DR. OSTROFF: Thank you.

CAPT. YUND: He has trouble with it himself sometimes.

(Laughter.)

DR. OSTROFF: Thanks, Jeff.

Withers was always very easy.

COL. GUNZENHAUSER: Good morning. I'm Jeff Gunzenhauser from the Army's Surgeon General's Office.

I spent many years out at Madigan, and we used to have a saying out there that at least in the Army Medical Department, you were either at Madigan or you wanted to be at Madigan, but now since I've been out here on the East Coast and they've finally got me out here, it's really been an exciting time.

I think I last spoke to AFEB maybe ten years ago on some respiratory disease issues. It's a pleasure to be back, and I look forward to working with all of the Board members very much.

I might answer one question Dr. Herbold asked about flu vaccine for trainees, and based on our initial estimates, we believe in the Army we have enough vaccine in the early delivery to cover our trainee base. So they're actually the fourth priority behind operational forces, health care workers, and high risk beneficiaries. Trainees are fourth, and we

believe we have enough vaccine in the first delivery to cover those.

So this year we're in a much better position than last year.

I'm just going to cover three topics this morning. The first one I'm just going to cover very briefly because Dr. Diniega has reviewed this.

We, following the policy that the JPMPG developed earlier this year, the Army developed its own tetanus vaccine policy, and you can see here that was published in the 4th of June, and basically the prioritization scheme is exactly what the JPMPG advocated and also the same as the ACIP recommended.

One thing that we did put in here that is an issue, and I hope we won't have to get into this, but if we do run out of tetanus-diphtheria vaccine, then we're going to be looking in some situations of maybe just using tetanus toxoid.

And you run into some issues there of hypersensitivity reactions if you use a diphtheria, tetanus-diphtheria booster sooner, and we've put some guidance out regarding that.

The second policy I was going to mention, I know there's been a longstanding recommendation for all of the services to screen for varicella and to

immunize trainees and other groups, and we did sign off on a policy this summer in July which implements a vacs. (phonetic) varicella screening and vaccination program, and you can see the populations that are targeted here.

There's a little bit of different guidance for the different populations. For the trainees themselves, we have a mandatory program. It's called the Varicella Screening and Vaccination Program, actually developed by Dr. Niebuhr while he was Preventive Medicine Officer at Fort Knox.

And we've reviewed that real extensively and have adopted the procedures that were used at Fort Knox.

The Army has adopted the option for the trainees to go with a history as opposed to screening all trainees serologically. It involves answering a simple question of whether or not you've had varicella, and the responses that are possible are yes, maybe, no, and I don't know, and we count those that say yes or maybe as a positive history of varicella.

And those who say no or don't know are screened, and if they are found to be non-immune, they are vaccinated. And that's been found to be effective

based upon the work that was done at Fort Knox.

We have a relatively aggressive program. We're trying to vaccinate everybody by day number three. The policy that's recommended is to initiate vaccination within the first two weeks.

Funding is somewhat of an issue. We've actually found, and I think this information was presented earlier to the AFEB, that there's a net cost savings to the Army through vaccination. Most of the cost savings has accrued on the operational training side with a net loss really to the medical activities.

And even though the overall is a net savings, we felt it necessary to reimburse the medical activities for the costs incurred as a result of screening. So we've identified that as a funding requirement, and that is working its way through our resource management channels, and we expect it will be funded.

This policy takes effect on 1 October, and I'll be tracking it to see how well it's implemented. Our focus is right now primarily on trainees, but we're also looking at other beneficiaries in accordance with ACIP guidelines.

This is just a summary of the net cost, and you can see here that for the Army Medical

Department we estimated a net cost of $252,000 and the amounts to the various treatment facilities are shown there, and that is what we're hoping to reimburse them this year.

The last area that I wanted to update the Board on is acute respiratory disease surveillance programs, some guidelines that we published this summer.

I think many of you are familiar with the Army's Respiratory Disease Surveillance Program. This has had a longstanding tradition which originated actually in the '60s and '70s as part of the adenovirus vaccine development program, initially intending to identify emerging strains of adenovirus which might require further vaccine development.

It was found to be very successful for a number of programs. So this has been ongoing for a long time.

The last time this policy was written was in 1995, and my understanding why we revised the guidelines was because of the changes that managed care brought in a specific aspect of our surveillance program, and that was that historically these guidelines mandated that trainees that met a certain clinical case definition, temperature over 100.5 and a

flu-like illness with any respiratory symptom, had to be hospitalized.

And that was wonderful because we were able to identify those cases and count them, and we could keep very good track.

However, with managed care changes recently wit an emphasis on out-patient care, nowadays many of these trainees are not hospitalized. Some of the basic training centers on their own initiative have set up various ways of taking care of these trainees, generally keep them out of the barracks and putting them in infirmary type situation, not in a hospital, with some supervision and management.

But the cost of that is they're not captured on the surveillance side. So we revised our guidelines and said you should count trainees who have lost duty time of eight hours or greater or have had some type of profile, a limitation of duty specified.

And so we're capturing those cases now, and that was the main purpose of the revision this summer.

For those of you who are not familiar with this, we do require weekly reporting, and there's a number of things that are counted, the number of trainees, the number of those that have respiratory

disease, those that have a throat culture done, and the numbers that have positive throat cultures.

And we have certain indicators. You'll see later when we talk about non-vaccine approaches to respiratory disease and adenovirus control. I'll show you a little bit about some of these indices that we track the ARD rate particularly, and I'll show you that later.

And we've also defined some response measures in event of an outbreak.

So those are the three items I wanted to cover for this report to the Board. I'll be glad to take any questions that you might have at this time.

DR. OSTROFF: Yes, I do have one quick question. With the varicella screening do you have any information about the ones that say, "No, I don't know," what percentage of them turn out to susceptible?

COL. GUNZENHAUSER: My understanding is that even those that say no or they don't know, it's still about 70 percent.

Do you have information on that, Doctor? Is that not correct?

Right. So 70 percent are immune and 30 percent are susceptible. So they end up being

vaccinated. I think we've had several studies that have looked at that,and that's pretty consistently what's been found.

Are there any other questions?

DR. OSTROFF: Other questions?

DR. DINIEGA: I have one.

Jeff, on the ARD surveillance, the capturing of limited duty or removal from duty for eight hours, is that being done through the surveillance system or administrative surveillance of some sort?

COL. GUNZENHAUSER: That's being performed locally, if I understand. The question is who's capturing that information. We do not have a computerized system that captures the duty status of our active duty folks. The way that is accomplished is on the ground. The preventive medicine staff at the five Army basic training centers are working with the clinics and saying, "We need to have information about who you've given a profile or who's got limited duty," and collecting that data daily, and that's how it's being reported.

DR. OSTROFF: One last comment since tetanus has come up several times. New York City didn't have any problem getting a hold of a

significant amount of tetanus. So my understanding was they got about 80,000 doses.

DR. DINIEGA: There was a notice that went out that said, immediately following the crisis, that the company had redirected and has stopped distributing until they could see what the needs were for the immediate consequence management of the medical needs.

DR. OSTROFF: Thank you.

COL. GUNZENHAUSER: Thank you very much.

DR. OSTROFF: Our next presenter is Colonel Bradshaw.

COL. BRADSHAW: Okay. Colonel Bradshaw, and I'm going to be trying to speak pretty quickly on this since I have a few things I'd like to go through with you on it.

And I just want to acknowledge my colleagues. I have preventive medicine resident Mylene Huynh, who's here at USHUS (phonetic), who's been rotating with us, helped with this development of this presentation; also Vic Macintosh who's back at the office covering the home front, and so I just want to give them some credit.

These are things I want to talk about. I'm speaking primarily about immunization topics

today, but I did want to cover some preliminary results we have looking at kind of an evaluation of how last year went with the influenza prioritization issues and the delays that we had in delivery of vaccine.

So we did an assessment of that plan and also are looking forward to what we're going to do this year to deal with some of those issues since they'll still be a sequential delivery of vaccine, albeit maybe not as delayed as last year.

We also want to just mention briefly the yellow fever vaccine safety study that we're planning, and also progress on the Air Force Child Immunization Registry.

And lastly, just to brief you about some transitions in the preventive medicine community here in the national capital area.

This is just a quick review. I'll differ just a little bit with Colonel Gunzenhauser. The priority one actually has several groups contained within it, but these were all to be immunized simultaneously in parallel. So there are a large number of groups there, some being operational considerations and others being high risk medical concerns.

But all of these in the plan last year were to be immunized first off in parallel, and those are the groups right there that you see in that grouping.

Next category actually was the trainee population. So they're really second in our prioritization scheme, and I may need to talk with Jeffrey about how he figures out this year he's going to be able to get them all in the first round because we didn't figure out how to do that this year, but they all should get it in the second shipment.

The third category, of course, is other groups that would be in contact with the high risk patients found in the first group.

The fourth being active duty military and priority for deployment or what many of us would have called mobility, then other active duty members with age stratification, and then lastly other beneficiaries.

I just want to remind folks that this is the reason behind some of those categorizations, and one thing I want to point out is age is one of the most significant risk factors. It's kind of a U shaped curve, and those that are over age 65 actually have a higher risk ratio for hospitalization and also

mortality than even people with chronic health problems that are younger.

And you'll notice later on in some of the evaluations that there's some confusion about this, I think, out in the field in terms of how things were done in actuality despite the way we prioritize them with health affairs and from the service levels.

First I'm just going to speak briefly on some data that we got out of AFCITA. Again, this is preliminary, and we plan to do some additional studies on this later, but I want to show you just a little bit of things we've been able to find by using our utilization registry information.

And then secondly we'll talk about survey results.

We looked at it by age since age was a consideration in risk factors, in particular, and this kind of a Paredo chart. Later on we'd like to do some survival analysis, but this is just a Paredo chart looking at cumulative numbers of people immunized over time.

And you'll see that the age over 65 did get vaccine ahead of the rest of the group, in general, and so there was a little bit of lead time, and people did manage to prioritize some of these

individuals. So at least that's some encouraging information.

When we actually look at it by status, military status, however, there are some interesting things that popped out. In particular, you'll notice even though the trainees were second in the list, the cadets at the Air Force Academy actually received it before anybody else, and this is very clear.

And I did go back and actually check with some of the folks at the Air Force Academy and found that that was a policy change locally that kind of preempted, I think, what we had put forth either from Health Affairs or from the service level.

So that was something we were able to find out just by looking at our immunization registry.

The other is kind of clumped together, although you did see that the Reserves seemed to get vaccine after everyone else.

PARTICIPANT: Is that 100 percent of the people, I assume?

COL. BRADSHAW: We also did a survey that we sent out, and we actually offered this to all of the services to do, and we have gotten responses from all of the services. But I should mention that the data we have so far, about three fourths of the

response are from the Air Force so far.

We had an n of about 50, and we're actually probably still collecting some data. We were doing this even up to yesterday. So this is hot off the presses, I guess we could say.

Almost all of the people were aware of the flu vaccine prioritization plan from last year. So they can't at least plead ignorance, or at least they say they weren't ignorant.

And most of them said it was clear and understandable. So I don't guess confusion would be the complaint.

And actually most of them said they also implemented changes locally in response to that prioritization plan.

We also emphasized last year trying to catch people up on pneumococcal vaccine. This was an emphasis in CDC and the ACIP and others to try and catch people since we knew we were going to be late with the flu nd since a lot of these things run together. And most of them also did that. So that was good.

Now, this is just how the prioritization went out. We asked them to rank these different categories, and we actually put them in order for

them, but without a ranking. And despite that there were some interesting things that kind of came out.

They did seem to be able to figure out that most of the operational needs and the high risk chronic medical categories should be done early, but I think the thing that stands out from this particular slide is that those over age 64 and pregnant patients seem to be ranked much lower, even though we intended for all of these people to get first priority and to get vaccine at the same time. So I think that's the carry home from this slide.

For the other groups that ranked below the priority one, this is how things came out. You'll notice that I think it's a little hard that we train people so much that readiness is the main thing as it's kind of hard to ship their thinking here. So the active duty on mobility actually is the highest ranking in this group.

The others fall out. Several clump together sort of in the middle, and then the other beneficiaries fall out where you would think they would at the bottom.

But just another way of looking at this, if we actually did this ordinally, it turns out that trainees are kind of lumped towards the bottom even

though they are kind of grouped closely with some of the others.

But as was mentioned earlier, the Air Force Academy and the cadets rearranged that priority and made them first.

The other contact high risk persons ended up three, active duty on mobility second, and the others, you see how they fall out there, but just some interesting things to see how the ranking in reality turned out.

Some other observations we had, and again, I'll stress this is preliminary, and we're still going back through the survey data, but we notice that mass immunization and a reminder recall was mostly used for active duty. It's kind of the thing we've always done. We've called people back by unit, and we've put them on a shot line where they've come out to the work site and done the work site immunizations.

They use provider recommendations mainly for the high risk patients in those categories, and other means, although we had things like standing orders and protocols and some other things that they could have used to signify if they had used any of those, they were not seen to be used as much.

Some of our early conclusions based on

this is that the first priority groups, again, were accurately identified, except for the 65 and older and pregnant patients. One of the things that we've gotten early already back from the field is the perception that because things were so delayed and that Medicare patients have access to getting their shots at the local grocery store, that a lot of them did that. And, in fact, there are some places like Luke Air Force Base in Arizona where we have a lot of retirees that said they have a lot of vaccine left over at the end of the year, and that may be, indeed, what happened.

I know even in my own office my colleague, Vic Macintosh got his shot for ten bucks, I think, very early in the season from a civilian source, and I got mine on the 17th of January being in the Air Force Surgeon General's Office.

(Laughter.)

COL. BRADSHAW: Of course, I was very closely watching the CDC reports on influenza in Virginia.

But the previous emphasis, as I mentioned before on active duty seems to persist in the local ranks. Some local medical decisions to reprioritize, we mentioned that, but I think we could increase our

use of reminder recall quit a bit.

This is some of the things we plan for this year. We want to provide a one-page summary of the rank order DOD prioritization plan basically using the categories that I showed you earlier.

We want to post the CDC flyers in all clinics that alert patients to the issues and who's at high risk, and not only that; provide the ability to self-report using a CDC developed questionnaire so that patients can identify themselves to their providers and also to the immunization clinic.

We're also in the Air Force going to and already have, in fact, gone back through the in-patient and out-patient databases looking at ICD-9 codes that are for high risk medical conditions,a nd we've identified those by individual. We're going to provide that list back to the military treatment facilities and allow the local military treatment facilities to do reminder recall.

The limitation here, of course, is that when patients are going through the clinics, you may catch the ones that are coming through, but if they don't come through in that two to three-month window, you might miss them. So we want to do reminder recall if we can.

We also want to do enhanced statistical and more detailed statistical analysis. We'd like to probably do some survival curves looking at some of these groups and categories; maybe also look at it by location, et cetera.

And we'll reassess and maybe do the same drill at the end of this season. So this is just some information of what we plan.

Just very quickly, the yellow fever vaccine safety study, as this was mentioned earlier by others this morning, but there were six deaths associated with yellow fever vaccine. Since then they've identified at least one other case that they know of that's probably associated.

ACIP currently did not make any changes, but they're reassessing, as Colonel Diniega mentioned. This is an issue for us as the Navy and the Marines vaccinated all essentially with yellow fever. I think FORCECOM, Colonel Gunzenhauser says, also has that police.

The Air Force currently does mainly mobility, but there are some of our operational people that probably get it on a routine basis, and we were actually thinking because of logistical considerations in the previous safety of the vaccine of going more

aggressive with this across all services.

So this puts a little cautionary note on that, but basically what we're going to do is use the immunization registries that we have to look at health utilization within ten days of having received vaccine since that seems to be the window for this kind of organ failure, and we'll be able to compare that with the number or people that we have in the immunization registry, maybe get some incidence rates and also just get a better look at the safety profile.

And we're working with the folks that do the vaccine safety data link studies at the CDC and the defense medical surveillance system, Colonel Rubertone and his shop, to do these studies, and hopefully that will help the ACIP and perhaps AFEB guide us on our future policy with yellow fever vaccine.

Just lastly I want to briefly mention that the Air Force in about 1998 went to doing active duty documentation of all immunizations in our immunization registry, and as of July of 2000, we've made that same move for all of our beneficiaries, not just active duty.

And part of that has, of course, been transcribing some of the older immunizations, but we

gave folks a year to try and get up to speed. And one of this is that the child immunizations is the top priority and the priority for prevention. Many of you may have seen in the American Journal of Preventive Medicine the study that was done by the Partnership Prevention and others on establishing priorities for prevention and child immunizations is right at the top.

So we want to try and be able to do the HEDIS metric actually across DOD, but in the Air Force we felt like the immunization registry was an important tool to do that.

So we have put this in, and this is where we are. You notice there's a very broad spread by military treatment facility, and some facilities have gone above the HEDIS average, but many of us are still trying to get there, and this probably just reflects the work that it takes to get this stuff in.

But I think we've made a lot of good progress, and I think this is going to be very beneficial to us in documentation and also being able to later look at safety with children's vaccines, perhaps participate in future vaccine safety day link studies (phonetic) with CDC and others for our kids.

Lastly, I just want to let you know that

this may be my last meeting as a formal AFEB representative for the Air Force. However, I hope it's not my last AFEB meeting. I am going to be going over, as it looks, to the Global Emerging Infection Surveillance and Response System.

Lieutenant Colonel Kelly Woodward, who's currently at the Population Health Integration Team, is going to come over and take my place. Lieutenant Colonel Vic Macintosh will remain there, and all of this should happen about hopefully by the first of November.

So I just wanted to let you know that, and you might be seeing some new faces here at the meetings.

Any questions for me?

DR. OSTROFF: Well, let me just start by saying that, Colonel Bradshaw, we will certainly miss your presentations. They've always been very insightful and wonderful. And good luck on the new assignment.

COL. BRADSHAW: Thank you.

DR. OSTROFF: Questions?

Pierce, do you have any comments about yellow fever sine it's come up several times?

DR. GARDNER: Well, it's, first of all, a

surprise that this is the oldest vaccine we use, and up until a couple of years ago, we thought beyond about six months or seven months of age it was pretty much completely safe. To have these happening still requires an explanation. Looking at the manufacturers and all, they haven't found much.

The problems have almost all occurred in elderly people. So I think that the concern for the troops, active duty troops, we haven't identified a problem in that age population at all.

But I do think it's a big issue for travel clinics and particularly the elderly, but I think it's not a -- I would make one anecdote. I had to write something about yellow fever a few years ago. So I called CDC and I said, "When was the last case of yellow fever in a U.S. citizen?" This was 1992. We've had a few cases.

And they said, "Well, call Greeley, Colorado or Boulder."

DR. OSTROFF: I know the date.

DR. GARDNER: And so they said, "Call there. The repository of the world's wisdom of yellow fever is Tom Monath, who'd love to go into private industry."

I finally tracked him down in Boston.

This took a while. So I finally got hold of the guru, and I said, you know, "What is the meaning of life? When is the last case of yellow fever?"

And he said the last documented case -- this is in '92 -- that he could find, I think, was 1928.

DR. OSTROFF: '27.

DR. GARDNER: We had gone 65 years roughly without a case.

So I said, gee, I'm glad it's a very safe vaccine because I'm sure there are a lot of people, backpackers and all, who slipped through the system.

So we would require a very high level of safety of this vaccine, and it is disturbing for the elderly to find this happening. But I don't think it's a big issue for the military.

DR. OSTROFF: Well, there are a couple of things. One is that there have been a couple of younger --

DR. GARDNER: Yeah, they've had cases now.

DR. OSTROFF: -- cases of this, and that's been in Brazil.

DR. GARDNER: Yeah, and Venezuela.

DR. OSTROFF: And we don't know if that's something that's unique to the Brazilian vaccine,

which isn't the same one that's used in this country. I think it's a different vaccine.

And since over the last couple of years we've now had a series of international travelers who have come down with yellow fever, and part of the problem is that yellow fever is an emerging infection that's definitely on the rise.

We're about to send a team over to Abidjan to look at the first occurrence of urban yellow fever in a setting in quite a while, and so it's a significant issue.

COL. BRADSHAW: Yeah, I just might add that we're working with Marty Settron at the CDC on this, and the seventh case that they identified as an Equadoran who was here in the United States studying, but he was, but he was also 20-something.

The two Brazilian cases was a child and a 20-something year old woman, but the case here was an Equadoran who received the vaccine here in the United States to go back home, and then had organ failure, but fortunately he survived, but they were able to document with tissue samples that it was vaccine strain.

DR. OSTROFF: Other questions? Phil.

DR. LANDRIGAN: Yeah, this is Phil

Landrigan.

I'd like to go back to the influenza thing. It's clear that we were very lucky last year. We were caught with very little vaccine, and we were just fortunate that we didn't get hit with very much of a very aggressive strain.

But have we done a good, careful postmortem of what went wrong at that time so that we can hope to prevent it in the future?

COL. BRADSHAW: In terms of the manufacturing process and all of that?

DR. LANDRIGAN: Yeah, why it went south when it did.

COL. BRADSHAW: You know, obviously there's others that can speak to this. I participated in the influenza, and still do, in the influenza pandemic planning at the national level, and of course, this is a concern with everything, but a lot of it was at least for the military that our primary supplier was Wyeth Lederle who had significant problems in production, and those weren't all just problems growing the Panama strain because other companies did not have that problem as much. It was an issue, but some, like Mediva, last year were able to get their vaccine out very early.

In fact, the DOD had 230,000 doses of vaccine from Mediva early at the usual time when you normally get it, but our majority supplier last year was the one who had FDA good manufacturing practice problems, and so that that was a problem, still is, I think, to a certain degree.

I think those issues remain, but people are trying to address them, you know, as much as possible. It's certainly an issue in trying to ramp up production, I think, early. If we have a pandemic strain and we want to try and get that out and get it plussed up, getting the manufacturing capacity.

We had four manufacturers before. One of them went out of business altogether, and so we now are left with three. So it seems to be a problem, and of course, we've talked about many vaccine production problems, and I know Joel Gaydos helped get the U.S. Medicine Institute looking at some of these issues, and we're looking at issues with government owned, contractor operated facility in the military, but we still have a lot of hurdles, I think, to jump to get there.

DR. OSTROFF: Yeah. I mean, as Dana said, it was basically a combination of the fact that two of the manufacturers were having GMP problems and also

that the H3N2 component was somewhat slow in terms of how it grew, and it seems to be that combination that caused this to happen.

The GMP problems are what drove one of the companies out of the business. So one of them is still having some difficulties related to that.

Based on what's going on in terms of surveillance data, we still don't see a lot of H3N2 activity going on around the world, but we got really lucky last year that it was such a mild flu season. I doubt it will happen two years in a row. It's got to show up at some point..

DR. GARDNER: I think one of the big variables to the system is that the different viral isolates grow in eggs at different -- some grow well, and some grow much less well. So the problems of getting the density of virus up to speed is a crap shoot a little bit each year, along with whether we guessed right.

So it's one of the variables in the system until we get to a different vaccine or grown in a more reliable system, I think we will be faced with this every periodically.

DR. LANDRIGAN: Are folks working on the development of such systems?

DR. GARDNER: Yes. It's quite a lot of -- everybody recognizes that the system is prone to variation in supply because they're on a very tight time frame by the time they decide what's the vaccine going to be this year, and there's not a lot of leeway for anything to go wrong.

DR. OSTROFF: Well, hopefully the live vaccine will get us away from some of these problems.

Other questions? If not, let's move on.

GEN. CLAYPOOL: I'd just make a comment. You know, communicating health risk is such an important part of the Department of Defense's force health protection program, and I don't know how many of you are aware, but General Lester Martinez chairs an interagency working group that deals with communicating health risk. It has members from Department of Defense, Veterans Affairs, and Health and Human Services, and it's actually international, too, because I see Dr. Maureen Fensom sits on it from Canada.

And I think I'm going to talk to General Martinez, but it seems to me that there's an opportunity to work together in communicating particularly influenza, and CDC has an excellent satellite broadcast capability, advising health risk

of influenza, in addition to the fact sheets that you mentioned.

And I think as we also look at yellow fever when that issue is resolved, communicating the thimerosal issues, I think there's an opportunity to work together to do that.

So I think I'll ask General Martinez perhaps to see if he would head up a cell to look at this.

DR. OSTROFF: Good idea.

Let's move on and try to get through the other presentations.

Captain Yund.

CAPT. YUND: Good morning, everyone. I'm Captain Jeff Yund from HUMED (phonetic). I'm going to try to turn a few of my 9.3 minutes back in to try to get us back on schedule a little bit.

I have a little bit of good news about adenovirus vaccine. We are very close to having a contract be signed with a manufacturer.

Now, I guess the flip side is that we're still looking at probably five or six years till we have vaccine ready to give to recruits again, but that's, I think, some good news anyway.

Tetanus toxoid, I don't think I need to

say too much about that. We're going to have to just work through the next couple of weeks and couple of months since a fairly large amount of the product went to New York City, and we'll see how that goes.

Influenza vaccine we've talked about. Just another example of a vaccine shortage that we're seeing. A brand new or fairly new vaccine, Prevnar, I saw yesterday is going to be in very short supply for a period of time.

I wanted to mention just a little bit about the fall on leukemia cluster that I briefed you on at the last meeting. There's a lot of activity there. CDC, starting its case control study and ATSDR assisting with the environmental sampling part of that study.

Fortunately there have not been any new cases since May. There was unfortunately though a second death among the 14 cases in the cluster.

Near future crystal ball. What I'm referring to here is in the wake of last week, I think all of the preventive medicine folks in DOD are starting to look ahead into the next couple of weeks, couple of months to see what sort of preventive medicine sources or resources might need to be deployed. It's too soon to know exactly what's going

to happen, but we're starting to look in that direction to see what our contribution can be as we move through the next response phase.

And unless there are any questions, that's it for me.

(No response.)

CAPT. YUND: Okay, great.

DR. OSTROFF: Thank you.

Dr. Schor, Captain Schor.

CAPT. SCHOR: Good morning. It's really good to be here especially when our building, which is the Navy Annex, was about a four and a half story. The jet on terminal guidance that went into the pentagon was about four and a half stories above me in a four story building, and we actually felt the pressure wave from the jet as it went over top of our wing. So it's really good to be here, and I really appreciate everybody that traveled here to come to this meeting. So thank you very much.

The other thing is the challenge of being number five to brief is my very able colleagues cover a lot of ground, but the fun of that is that my ability to get out of the box and cover some other topics makes it all that much more fun.

So if I could have the first slide, maybe.

We don't have anybody up in the control room.

CDR. LUDWIG: They're having a problem.

DR. OSTROFF: Keep ad libbing.

CAPT. SCHOR: We'll keep ad libbing. Okay.

What I wanted to do was start with -- provide a little bit of an update on some of the injury prevention efforts that I brought forward to you last May.

And slightly less than a month after that briefing myself and a Preventive Medicine resident, Commander Fred Landreau, were invited to brief the Marine Corps Executive Safety Board, which consists of 21 flag officers wearing a total of 27 stars by my count, and despite the fact that these generals had been up till 01 in the morning before, and Fred and I were at the north end of a southbound briefing train, w were at 1500 the next day. If I never have a more positive experience than that experience, I will be very happy and feel very comfortable as having contributed something as part of a career.

If I could have the next -- go two slides forward on, please. Can I have the clicker? There it is. Now I've got control. Okay.

So this is what we briefed. I gave you a

heads up on that last time.

One of the things I did, I introduced basic, the injury pyramid and started out with the safety pyramid that goes with Class A, Class B, Class C mishaps. Class A are deaths or costs, I think, over $1 million of loss of materiel.

Also you obviously have the public health model, but I made this apply to the commanders. These are the kind of categories that Marine commanders and most line commanders have to deal with from a personnel standpoint. So we tried to make it very applicable to those commanders, and we're still working in this basic model.

We briefed on right below deaths, disabilities. Those numbers are general estimations on musculoskeletal injuries. We think we can get data on administrative separations and perhaps some limited duties, but we're trying to put this in a model that the commanders can work with and also can brief them on where sports medicine interventions kind of work at, say , the second and third layers from the bottom, and how looking at that level of the pyramid has a great impact at the higher echelons where it's very costly.

We did some calculations. If we prevented

about a third of the musculoskeletal disabilities in one year, it may save in the order of $16 million. So it's kind of cost effective for the bean counter.

Just a couple other comments about that. We've gotten excellent support through Dr. Ostroff's help from the CDC, National Center for Injury Prevention and Control. There's an ongoing liaison there.

We now are data rich. We have complete data from 1996 to the present on all injury attritions and all attritions from the Marine Corps and are just starting to look and analyze that and getting some more MPH projects to help us out with that and other residents in preventive medicine.

Very interestingly, a lot of the advocacy that I've been working has also synced up with some leaders who are ex-recon. Marines, and there is an advocacy for a Marine Corps order on wellness. Now, that's a very interesting thing to consider for the Marine Corps.

There are two things that the general said as he held a meeting for us down at Quantico. One is that the Marines are beginning to realize that their leadership ability is being measured by their PFT score so that as they select for command or sergeant

major, if it's between three Marines, the fellow that has the best PFT score gets the job.

They realize that may not be the right measure of leadership, even in the Marine Corps. So they're relooking at some of those things.

Also, they're realizing that the price of service should not be a broken body, and so they want to return well and able Marines to the society in order to continue their contributions to society as Marine veterans or Marine retirees.

Finally, I'll just mention a couple of the goals. Trying to continue to work on self-sustaining the analysis and research, and also trying to bring in this aspect of sports medicine to attack the lower levels of that injury pyramid.

And now to some current events. Just to give you some idea with what we're doing down at Headquarters, Marine Corps, without going into a lot of detail because of maybe security considerations, we're helping a lot of our displaced shipmates. The Navy is dealing with this as it would at sea. They're dealing with it as a damage control process, and they're fighting the ship. They fought the ship that was attacked last Tuesday.

Everything is working well, but they're

working very hard, and the Marine Corps has been there to support them.

This has demonstrated the many faces of prevention to me. I've been very involved with conduct stress prevention. I'll mention something on the next slide. I've been supporting the Navy SPRINT team, which is the Special Psychiatric Response and Intervention Team from Bethesda. We've gotten them involved with the senior Marine Corps leadership, and they are very busy debriefing large subcodes within the OPNAV staff to deal with some of the personnel losses that the Navy has suffered.

And basically I can only assure you that the Navy and Marine Corps team is strong and ready to go in this what I would call is a -- if we just got off the Cold War, I'll call this the "Shadows War."

This is about 90 percent of the text of a flyer that was put up by the SPRINT team, and it gets to that idea of reconstituting the fighting force of the Navy staff, and you have that in a handout.

Some of my thoughts on some of the implications. If people don't understand what asymmetric warfare is before, if they didn't understand what it is before, they should understand what it is now.

I go to my prime intel. source, which is the Kiplinger newsletter, and it talks about other kinds of threats on its special edition of last Wednesday: cyber sabotage, contamination of water, poisons and biological pathogens in HVAC systems, stadium explosions, sabotage of nuclear electricity generating plants, all of these sorts of things; small scale nuclear bombs made from stolen atomic fuel.

These are some of the threats that we have to think the unthinkable.

I think that from a force health protection standpoint I'm not sure this is a young draftee's war that was the concern of many folks at my church this past Sunday. It's going to be a lot of folks involved.

I think we have to address the issues of vaccine availability, and some of the statutory barriers to employing countermeasures, such as INDs, and that's on the schedule.

And just a warning. As was reinforced last Wednesday morning by our senior leadership, all of us are in this. All of us are in this for operational security, and we have considered that we are at war since last Wednesday or last Tuesday actually.

And maybe those of us in public health, preventive medicine, and medicine in general may be the soft spots that the terrorists try to get information from.

So I encourage you to all assume that your E-mails and your phone calls may be sources of information.

And then I would just like to say perhaps where the Board may be very critical to this process, these are just my thoughts. You can help us think asymmetrically. Some of us here in D.C. may get into group think. Maybe you can help us stay away from that.

Think of some of the vulnerabilities that we may not think about, and that as we have seen last week, the Homeland Defense requires a strong partnership, and I think this Board is very important for that.

Thank you.

DR. OSTROFF: Thank you for that presentation.

Again, I think all of the Board members would say all you have to do is ask us. We are always available to provide any assistance that we conceivably can.

I think in the interest of trying to keep on time since Lieutenant General Peake has arrived, what we'll do if we can is hold questions and maybe you can address them during the break.

Why don't we move on to Commander Ludwig?

CDR. LUDWIG: Good morning. Too much technology.

I'm starting off today with the implications of this national disaster to the U.S. Coast Guard. I made up my slides yesterday, and so it was really first and foremost on my mind.

As I've told you, as I've told this group before, every day, everywhere, the Coast Guard deploys. It's nothing new for us to deploy in our mission, our day-to-day mission.

However, what we have now is some deployments in the sense that usually the DOD thinks of deployments, and that is a couple, several of our port security units have been called up. We do have a Homeland Defense mission with the Coast Guard. I think it's been in the news so that I don't have to elaborate on that.

But one of the things that's unique about our port security units as opposed to most of our other units is that it's at least half staffed by

reservists. So a number of Coast Guard reservists have already been called up to take part in the port security mission, and one of our port security units is likely to be going overseas. We don't know yet for sure.

Anyway, with the mobilization of Reservists, we have a number of issues, although the units are responsible for keeping even the Reservists medically ready. We all know how things sometimes fall through the cracks with Reservists, and so I've sent out a lot of information in terms of some of the current issues that we have to deal with as well as just making sure that these people are medically ready to go.

The vaccination issues I don't think I need to go into anymore, except to say that for yellow fever there was never a question in my mind that we would make sure everybody was up to date. The question in my mind was although I know that this is a requirement, it's a mission requirement; our people go into yellow fever endemic areas frequently.

Do we have an ethical obligation to let them know about the problems with the vaccine? And at this point I have chosen not to raise that red flag, but I think it's something that needs to be discussed.

And then finally, with the issue of tuberculin testing I've talked to this group a couple of times now about the problems with false positives on mass testing with skin testing for tuberculosis, and I have recommended not to do a pre-deployment TST or tuberculin skin test on these people unless they are in a high risk category.

Finally, for the national disaster, the issue of disease and non-battle injury and environmental surveillance is a big one for the Coast Guard because we do not have a system in place yet. And I have been pushing for this, as well as we've been pushing a number of readiness issues and disaster preparedness issues. We have not been funded in the past. Now we'll see if some of these things hopefully might change.

Just a word about -- oh, how do I go back? Thank you.

Just a word about acute respiratory disease or febrile respiratory illness and adenovirus. At Cape May the line of real importance is the rate here, the blue line, and I will call your -- this is for all of 19 -- sorry; 19 -- 2001. I call your attention to the scale. It doesn't even go up to the epidemic threshold, which is 1.5. So we've had a good

year so far.

And the green line, I find it useful or interesting really to plot the adenovirus positive cultures that we've sent to the Naval Health Research Center. We pretty much get specimens from almost everybody who fits the case definition at Coast Guard. So I think it's reasonable instead of doing a rate to show just the number of positive specimens.

And I think it's kind of interesting, and you'll see another slide later that shows some parallels between the rate and the number of cultures.

The rest of the time that I have up here I'd like to spend talking about the Sexually Transmitted Disease Prevention Committee and specifically the Surveillance Subcommittee. The STDPC is one of seven Prevention, Safety, and Health Promotion Council, or PSHPC, committees.

I think most of you are probably familiar with the PSHPC and the level of support that it has. The Executive Council I was going to say includes the Surgeons General of the Army, Navy, and Air Force, the Assistant Secretaries of Defense for Health Affairs and Force Management Policy, and other such high level defense personnel, as well as Coast Guard personnel.

All of the uniform services are

represented, and under the PSHPC, as I said, there are seven committees, one of which is the STDPC.

Under the STDPC, there are five subcommittees -- boy, it's like you don't realize you're touching the button -- five subcommittees, only two of which are currently active. We are coming up to speed, and these two subcommittees have been very active. The one that I'm going to talk about is the surveillance subcommittee, which we call the STDPCSS.

For the whole committee it has been emphasized a number of times that surveillance is probably the highest priority of anything that the STDPC can be working on because we need good surveillance in order to target, of course, and evaluate interventions.

I think we all are aware of the importance of surveillance in this group.

All right. I'm doing something wrong here. Toward the back? These things usually work on the screen, too.

We have outlined the goals, objectives, strategies, and so on, and what I've put up here is the two major strategies or objectives that we're working on and the strategies that we're trying to achieve those objectives.

We would like to have some accurate, standardized surveillance of military STD incidences and basically the same thing for prevalences, and our first strategy is to basically identify and evaluate the existing surveillance tools for both incidence and prevalences.

As for the progress that we've made already, the service surveillance systems have basically been characterized and evaluated. The things that we've talked about, and we have this nice, large matrix, which I didn't want to try to put up because you wouldn't be able to see it, but these three items are the major categories of the things that we looked at for each of the service systems.

And in terms of prevalence, as we've collected, Dr. Gaydos really has done a wonderful job pulling together a big stack and bibliography of targeted prevalence studies, and we are in the process of writing up the report.

We had discussed presenting some of the data and conclusions at this point, I think, because I was not able to work on it this past week, I am going to postpone that, but I will update the AFEB on this periodically. Hopefully at most of our meetings I will update. And so next time I hope that we have

some more data to provide.

I will say though that at the U.S. Medicine Institute for Health Studies meeting that they're holding together with DOD, GEIS or GEIS on STDs, regaining lost ground and improving the future, Lieutenant Colonel Vic Macintosh, well known to this group, will be presenting some of the findings that we have in this group.

I also meant to mention this, first of all, with my slide on national disaster, that Commander Mark Tedesco, who has many times sat in my seat or what was his seat originally, is in New York at Ground Zero as the medical advisor to the management support team for the disaster management, disaster medical assistance teams, or DMATs, and he's been there since Wednesday morning, maybe Tuesday evening. I'm not exactly sure, and I've talked to him a number of times. He's doing well, but he is our Coast Guard medical representative to the effort.

That's all I have, subject to your questions.

DR. OSTROFF: Thank you.

I think we'll have to hold questions.

CDR. LUDWIG: All right. Yes.

DR. OSTROFF: Colonel Staunton.

COL. STAUNTON: Yes. If I may, I won't go to the podium. I have no slides. I have no need to.

Firstly, thank you for inviting me. I'm very honored to be here.

I will go straight to, firstly, my goal, which is that where possible, I wish to foster cooperation between research in the United Kingdom and the United States. And so, therefore, I take this opportunity to make myself known to you so that if you wish to contact me, please do so, and I will insure that we get together with the right people on both sides of the Atlantic.

There are two concepts or two ideas which I feel may be of use, and one we have discussed already, and that is that we have used an initiative in the Army which has been a physician led project looking at working days lost, the gathering of that data to use as a tool to look at the means of prevention of injuries and of fast track treatment.

We have found that particularly useful, and in the future we're going to put advisors or certainly one particular advisor, Colonel Miller, in the United Kingdom, and I'm hoping that he will come over here and share with you the information which we have gathered and the differences it has made both in

policy in terms of giving information to the chain of command, which is useful, and therefore, in a sense de-medicalizing certain issues. And we have found that, as I say, to be extraordinarily useful.

So I hope that I can give the benefit of that work to you.

There is another area, which was touched on, and I think it is appropriate, particularly in the light of recent events that we should tackle again, and I should quote from Sun Tsu (phonetic), who said, "Kill one and frighten a thousand."

I think in the light of what is happening in our world today, this is particularly appropriate to us, and we should prepare ourselves, again, in the area of prevention and in the light of military wisdom and military history.

Right now a project with the Royal Marines started, and I know the Marine Corps is interested in, is in combat stress prevention and treatment, and again, we've emphasized de-medicalizing the problem. That is to say that our approach is not just in terms of preparation, but preparation of individuals within units.

So that peer groups can identify those at risk following traumatic events, and that the chain of

command, that is, the commander himself, instigates the work which will be done within the unit.

So as the medical officer and, indeed, the padre and other professional advisors are close at hand and are -- right at the beginning will give advice, we are actually turning the treatment, the looking after of people, the communication process we are turning over to peer groups.

So right now we run courses, for instance, and they are from full colonel down to marine. So those are two projects that we're working on.

And I must say that on the practical level, for instance, we are flying a team in from the United Kingdom this weekend, and I'm probably going up later on today or tomorrow certainly, and I'll be looking very closely at how in a sense the work we've been doing in the military we can apply to the civilian situation.

I'll take your questions if you have any.

DR. OSTROFF: Yeah, I think we'll hold the questions if possible, and thank you very much for your comments and your words of support.

Colonel Fensom.

LT. COL. FENSOM: Yes. I'll be short and hopefully keep you on time.

I have no formal report, but I thought it might be most useful for this group to have me give you my impression perhaps of what has happened, what is happening and what's going to happen north of the border with regard to recent events.

Last week, as the thousands of passengers were disembarked at Canadian airports, people from Halifax to Vancouver opened their hearts and their homes to these folks both in terms of comforting them and making sure that they were protected.

We deployed soldiers across the country to do that specifically, and we cried with them and with you.

What I am seeing now and what I expect to see in the future is a very unusual phenomenon of unity of thought between our public, our citizens, our military, and surprisingly, our politicians. There's a galvanization of determined will here that we haven't seen in Canada since World War II, and I wanted to make that very clear to this particular group; that we feel very much at war also. We're pretty determined to make this continent safe for us and our children.

And please contact me throughout any of this time if there's anything I can do to expedite

assistance or cooperation or any resources that we have in Canada to assist in this fight.

Thank you.

DR. OSTROFF: Thank you very much for those comments.

General Peake, I'll turn the microphone over to you for just a second. I know you have a limited time period.

LTG. PEAKE: Well, I just appreciate the chance to come over here. It's sort of a new word disorder since the 11th of September, if you sort of think about it, and you know, we spend -- we focused this Board on taking care of soldiers a lot in the past. Now we're really talking about the whole military family, civilians, contractors, that are all part of us, and in fact, there are a number of those that are amongst our casualties.

It does give us a chance to relook history a little bit as you mentioned, and you know, in some ways we've been here before when it comes to worrying about some of the threats, and we're in some ways not too much further along than we were 12 years ago or so when I was actually the chief consultant to the surgeon general during that time when we were wrestling with anthrax and bot. and PB tabs and things

like that, and we're still wrestling with them.

And you know, there is a sense of some urgency as we relook those issues, and I guess I would ask you to -- I've looked at the series of briefings, and I'm going to try to stay for Sal's brief here to listen to it as we dust off some of those issues, but you know the posture of anthrax now. We don't have an FDA approved source of the vaccine. We have the potential for getting one perhaps as early as this spring.

There are non-FDA approved doses available that are out there, and so the potential of using that is something that we will have to wrestle with.

And your thoughts on that and your links to the rest of the academic community as you understand the exigencies of our situation, I think, are very important. So it's worth kind of thinking through it in that context.

And you may have things that you think that we ought to be doing or ways that you think you might be able to help us that we haven't thought about, and I would encourage you to, you know, as you work through this meeting to kind of identify those things for us, as a matter of fact.

We have always had a tremendous

relationship with this Board, and your critical thinking and academic links allow us to be better as we work through this. We all share the same goal, and that's to take care of our people and keep them safe where we can, prevent their illnesses where we can, and identify the things that are going to keep them from being able to accomplish the mission that Maureen was talking about, and that's keeping us all safe here.

So I really wanted to come by. I wanted to thank you for what you've always done and what you will continue to do, but challenge you specifically to think about this new circumstance.

I'll give you an example. For our Reserve components, you know, sort of the mindset has always been, well, okay. We go off to war. We'll bring the Reserves in, and we'll have a steady mobilization and so forth.

Well, now in some cases the battlefield is their back yard. How do you mobilize? What should we be thinking about in terms of new policies in this new environment about protecting our reserve forces? You know, you don't have necessarily that mobilization build-up.

The National Guard were some of the first

people involved up there in the disaster area of Ground Zero, as you point out, and as I say, what things ought we be doing to our civilian work force?

I'll give you one example, is that we have not done DNA samples on them. We have in the military, and in fact, in this cohort, we've had quite a high group that we were able to pull off either their panographs or their DNA and be able to share that with those that are making the identifications.

But for the civilians, we're back to square one, you know, trying to find a parent in a child or two parents or a spouse and a child or multiple siblings or whatever, you know, the variety of patterns are that we can use to establish. So it's some of those kind of policies.

I would like to put a plug in for the notion about injury prevention. I appreciate that, the ongoing notion of that. You know, being focused by the recent events and the areas of the world and the asymmetry of the threat, revisiting this issue of how we deal with things that are out there in science that have the potential to protect our total force now are things that I think would be worth mulling over and thinking about.

And it may lead to some splinter meetings

to focus on them.

So I just would like to thank you for taking the time and for your support to what is, you know, as our President says, is going to be a long-term campaign.

Thank you.

DR. OSTROFF: Thank you, General Peake.

Let me just say once again we're here for you, and hopefully we will continue to be here for you.

And I'll also say that the IND issues are something that we at CDC are also grappling with in terms of the civilian sector and in one other way that you at this time are not in particular, and that's that we have the smallpox vaccine as well.

And in every way, shape, and form that we look at that vaccine, we're boxed in by IND issues, and I will point out that the vaccinia immune globulin is maintained by the military, and so there needs to be a lot of work in that particular area.

So I think what we'll do is move on to Dr. Cirone's presentation because the bulk of the presentation has to do with this issue of INDs, and it's a very important one, and it will continue to be an important one that the Board will have to have some

input on.

DR. CIRONE: Thank you very much for inviting me to make this presentation today.

This first slide is important things about this. This is all about people and Al Graziano prepared these slides, and I want to thank Al for giving me an opportunity to use his slides and to modify his slides.

The second item on this slide is that I'm a veterinarian. I'm a retired Army Veterinary Corps officer. One of the individuals that I had the pleasure to serve 30 years with lost his wife, and she's still missing. So this is about people, and it's with a heavy heart that we go through this entire week.

The other thing I wanted to mention is I just came from Sunday a tour on the Executive Support Center. The word went through the entire support center that General Peake had visited all of the patients in the hospital, and it was an inspiration to everyone, and so we appreciate it, and thank you for your leadership.

The right button? The purple one, too?

(Laughter.)

DR. CIRONE: All right. The left button.

Excuse me. Okay. I've got it now. All right.

Gulf War, 1990, 1991. In 1990, the interim final rule allowed the Commissioner of the Food and Drug Administration to be able to approve the use of investigational new drugs during military operations.

At that time Dr. Enrique Mendez was the Assistant Secretary of Defense for Health Affairs. Dr. Mendez felt that the enemy probably had chemical and biological warfare agents, and in order to protect our troops and to provide the best medical countermeasures, he felt that there was a need to use pyridostigmine bromide and bot. toxoid.

As a result, he asked the Commissioner of the FDA. The Commissioner of the FDA felt that these products were safe, showed promise of efficacy, and that there was reasonable expectation that use of informed consent was not feasible. He, therefore, approved these two products.

In the war, we did not do a good job of managing the use of an IND. Not surprising. I mean, in this day and age, just recently a number of medical institutions have also been faulted for using INDs in an inappropriate manner and in trying to follow the FDA ethical regulations.

So the FDA noted that these deficiencies existed in he use of these two INDs during the Gulf War. As a result, a series of events followed.

In July of '97, the FDA requested comments on the interim final rule from the public. Should we revoke the interim final rule? Should we finalize the interim final rule?

Shortly after that, Defense authorization bill, Title 10, stated that any time the Department of Defense is going to use investigational new drugs, we must notify individuals that we're giving them an investigational new drug, and we must document it in their medical records.

As the Department of Defense was discussing, waiver of informed consent and the interim final rule on whether it should be revoked or not, and having those discussions with the Department of Health and Human Services, Senator Byrd amended Title 10 to state that there was a requirement that the President of the United States have an option to use investigational new drugs in operational environments.

However, he upped the ante and basically said the authority to waiver informed consent would no longer be the Commissioner of the FDA. Only the President of the United States would be allowed to

waiver informed consent.

So he made that amendment in May. When the National Authorization Act for the Defense Department was approved in October, that was part of it.

So immediately the staff of the White House, the Office of Management and Budget, worked to put together an executive order. The following September, 1999, Executive Order 13139 was signed by the President, and it basically put forth the policy and the procedures that the Department of Defense would utilize in requesting a waiver of informed consent from the president.

Five days later almost, maybe six days, the 5th of October 1999, the FDA made changes to the Code of Federal Regulations, Part 50, and gave a list of standards and criteria, 18 standards and criteria that must be met before the Secretary of Defense requested a waiver of informed consent from the President.

Between October and December, in November of '99, my boss at that time, Dr. Sue Bailey, testified before Congress. They asked her to put forth requirements for training and to put forth a DOD directive to implement Section 1107 of Title 10,

Executive Order 13139, and the FDA regulations noted at 50.23.

She indicated she would do that, and the training plan was assigned in December of '99. And in August of 2000, the Deputy Secretary of Defense signed DOD Directive 6200.2, which is now our current policy. DOD Directive 6200.2 establishes the policy and assigns responsibility for compliance with 10 USC, Code 1107, Executive Order 13139, and the appropriate parts of the Code of Federal Regulation.

Important here is that it designated the Secretary to the Army as the DOD Executive Agent for the use of investigational new drugs for force health protection.

Of course, the point here is that we have the ethical responsibility to protect our deployed troops, and that we're going to try to provide safe and effective vaccines and treatments to negate or minimize health threats to our forces in the field.

We're going to try and use approved FDA products. However, if they're not available, if an IND is the best available protection, then we will use them. But first we have to go through the processes.

One of those processes is it must be approved by an IRB. There's only one IRB that is

authorized to approve the IND protocol. That's the tri-service IRB, the Human Subjects Research Review Board of the Army Medical Research and Materiel Command, the Surgeon General's IRB, the Surgeon General of the Army's IRB.

Once they have approved the protocol, it then must go forth to the FDA to be approved for contingency use, and prior written notice is required of service members.

What is that prior written notice? Service members must be notified of the use of an IND, a clear description of why the drug is being used, information on possible side effects, any other information that the FDA requires.

And then this notification must be placed in their medical record. And if they're given the IND, the fact that they're given the IND must be placed in their medical record.

This HSIRB is a special IRB in that the Code of Federal Regulations required that it be composed of three non-DOD members, and so this is currently the only IRB that we could utilize to approve the AFD protocol. We can't go shopping. This is the IRB that is the only IRB that we can use, and these are the responsibilities that they're required

to do that are noted in the Code of Federal Regulations.

As I indicated, FDA changed the Code of Federal Regulations, Part 50.23, which was the interim final rule which had to be modified so that the Commissioner is no longer authorized to approve INDs, and only the President of the United States can do that, and it sets forth 18 standards and criteria that must be met before the Secretary can request a waiver of informed consent from the President.

The informed consent must be obtained in advance unless the request for informed consent is waived by the President.

Before the President will waiver the informed consent, it must be noted that getting informed consent is not feasible, is contrary to the best interest of the member, or is not in the best interest of national security.

The presidential waiver in accordance with the FDA regulation must include that the member is confronted with a life threatening situation. No FDA approved alternative method exists, and the Secretary of Defense has determined that the waiver is in the best interest of the troops and of the mission.

These are additional requirements that

were placed on us. The IG, the FDA, and the HSRRB will continue to conduct ongoing review and monitor the use of the IND during the operations.

The Secretary of Defense will notify Congress and issue a public notice that the IND is being used.

The waiver will expire one year from the year of approval or if some time during that year it is no longer required, then that waiver is no longer effective. And the Secretary of Defense will notify the President if the threat changes during that year.

What service members will be told when they're given the IND, again, they must be told that it's investigational or unapproved for its applied use, the reason why the drug is being given, the possible side effects, including interactions, the means for tracking the use, adverse effects, risk-benefits of the investigational drug, and a written statement that the IND is not approved or the drug is not approved for its intended use.

If the IND is going to be used in theater, the CINC, the Commander in Chief of that theater of operation, will put a request through to the Chairman of the Joint Staff stating that he needs to use this drug in that particular operation.

The Chairman of the Joint Staff will then go to the Secretary of Defense for approval. This approval process will include within the Department of Defense going through the services, going through Health Affairs, going through the General Counsel, through a number of other offices at the Office f the Secretary of Defense level.

The FDA must have approved the IND. The requirements in the field will include appropriately trained personnel in the theater, maintaining accurate medical records, and accounting for all of the doses.

Current examples of things that we might use would be anthrax vaccine as a post exposure protocol, and in the current protocol as has been mentioned a number of times, and that IND post exposure use of the vaccine would be with ciprofloxacin.

Another possible use of an IND would be once again pyridostigmine bromide.

A couple of things that I want to mention because we use INDs all the time, and so I just want to make it clear that every day in our hospital facilities, medical providers, physicians, have the authority to practice medicine, and this does not allow them not to practice medicine.

And so on a doctor-patient relationship, doctors can still practice medicine and use INDs, you know, as they're authorized by their local state laws, et cetera. And also, this does not apply, the use of INDs when we're using them in our medical treatment facilities in accordance with the Code of Federal Regulations. Every day in our hospitals, physicians are treating patients with AIDS, with cancer, for various oncology groups, and we're using INDs in accordance with informed consent and with all of the requirements that exist in the current Code of Federal Regulations. And so this doesn't apply to those situations.

A summary of where we are. We must use FDA approved products if they're available. When at the time need for force health protection measures, if they're not available, then the DOD component, the CINC, may request approval from the Secretary of Defense to use an IND.

When using an IND for force health protection, we still must meet all of the requirements of 10 USC 1107, the Executive Order 13139, and all the applicable FDA regulations.

If we want a waiver of informed consent, only the President of the United States can grant that

waiver.

March 13th, 2000, the Assistant Secretary of Defense for Health Affairs asked the AFEB for recommendations for most appropriate antibiotics that would be used for treatment of anthrax, plague, tularemia, et cetera.

We thank you very much. August 3rd, 2000, the AFEB gave us a letter back with specific recommendations.

The reason I was asked to speak is the Board wanted to know what happened since. DOD has been working to get an approved IND protocol for contingency operations. We're currently working to get the concurrence within DOD of the use of the anthrax vaccine post exposure protocol with ciprofloxacin. A draft protocol is in coordination.

I say DOD. Actually Army is Executive Agent. Army has written up the protocol. The Secretary of the Army through General Parker at MRMC, they're the ones that ar really working this issue.

DOD has a working group to develop a draft implementation guidance to the CINCs in the services for an implementation of an IND protocol required. The CINC's surgeons came back and said, "Okay. We want to work with you to see if we can get a protocol

approved, but we don't have the expertise to really put together the implementation plans. Can you please help to put together the implementation plans?"

Dr. Clinton said, yes, he would, and he wrote a letter to the Secretary of the Army, and the Surgeon General of the Army has put together one of his staff officers to put together this. Colonel Schnelle has a working group that's working this, and I might mention on the first one, the IND protocol, Colonel Pierson from General Parker's staff is here today in case there are any questions about the protocol. He'll be here to assist me to reply.

Dr. Clinton then met with PhRMA, the Pharmaceutical Research and Manufacturers of America, concerning the AFEB recommendations. We noted that a number of those recommendations were off label, and we asked them if they could get together with the manufacturers of these particular drugs to see if they would work with the Food and Drug Administration to see if we could get indications on the label so that we would not have to use these antibiotics off label.

PhRMA sent the letter out to 30 manufacturers noting our concern, and Bayer responded, and Bayer said that they would put together a package for ciprofloxacin to see if they could get it approved

for post exposure prophylaxis and treatment of tularemia and plague.

I'm hoping that this package we put together sometimes within the next three or four months, and that hopefully it will be presented to the FDA, and then, of course, we have to see what the FDA says. They might accept it as it is or they may suggest that additional tests or studies are required, and we'll just have to take it from there, but we are working the issue.

The anthrax policy memo I just want to mention. It's out there. It's still in effect. It tells the services, you know, what they should be doing as far as anthrax is concerned and how to manage it and how to look at the current best medical recommendations that are listed, and it gives three references for medical recommendations for the use of anthrax, and we're letting the services and the doctors out in the field determine what they feel is appropriate.

What's the bottom line? DOD is seeking advice from experts. DOD directives provides the policy and implements the laws, the executive orders, the regulations. DOD is working to get contingency IND protocols for high threat areas or high threat

agents.

DOD is developing implementation guidance, and DOD is working with industry to get label indications with FDA approvals.

That concludes my presentation.

DR. OSTROFF: Thank you very much.

Let me -- Ben, you can, and then I'll ask a question. I have many questions. So why don't you go first?

DR. DINIEGA: Ben Diniega, Health Affairs.

I'd just like to say that this issue is very complex, and back in March we had an exercise run between OSD, the Joint Services, and some of the CINCs for a wartime scenario, and it was a wonderful exercise in that there was some play involve with the youth of an IND product in response to potential BW youth, and we really learned a lot during that exercise in the messages that went back and forth in taking a look at the problems we would have with an IND.

And, therefore, I really believe in exercises and the need to look at how we are going to do things, but the main point I wanted to make is that, number one, we can get a waiver of informed consent from the President, but we still need first an

FDA approved protocol, and that protocol, of the many steps that Sal mentioned, one of those agency requirements is informed consent.

That's the only piece of the IND protocol that is waived. So you would still need an FDA approved protocol.

The other major point, that it has to be written into the OP plans or the CON plans, contingency plans, of the theater before they can use it, and many of these things can be done ahead of time, and I think it's very important to make sure that the services and other people understand we can put a lot of this in place so that the execution piece will be the toughest part. How do we execute it during time of mobilization of war is the toughest part, but we have to get all of the other pieces in place.

DR. CIRONE: Thank you, Ben.

I might mention that Army Surgeon General and the Joint Staff sponsored a conference for a week in Virginia Beach to discuss a number of issues, one of which was IND issues, and at that time a list of all of the requirements, including the requirement to put all of this in OP plans was all formulated, and I think Colonel Schnelle and General Peake's office has

that list, and we're all working together to see if we can accomplish those requirements to get these things done.

Sir?

DR. OSTROFF: Let me ask a couple of questions. One is are there any initiatives underway to look at changing the legislation.

DR. CIRONE: The only initiative that I'm aware of right now, sir, is that in the current Defense Authorization Act, there's a Section 713 both in the House and the Senate on Section 980 of Title 10, which states that in the Department of Defense if we're doing research you must have informed consent.

And the House version of that kind of states that in an emergency or under certain circumstances it suggests that the Secretary of Defense should be allowed to waiver that and use the rules and laws that currently exist for everybody else who's doing emergency room surgery, and to allow DOD to use the same thing.

We didn't put that in, but whether or not that makes it or not, I don't know. We'll have to wait and see what comes out of the conference.

DR. OSTROFF: We can have those discussions.

DR. CIRONE: That's the only one that I'm aware of.

DR. OSTROFF: Let me just say that we've been very, very careful about distinguishing INDs from research. There are certain things that we are acquiring INDs for, that we are doing so not because we consider ourselves doing research; simply because FDA requires that they be done under an IND basis, and we don't consider them to be research.

DR. CIRONE: And the Department of Defense is the same way. If you look at my very first slide, I noted that we considered in the Gulf War and we still consider that this is treatment rather than research, but in order to use them, we must follow those rules and regulations.

DR. OSTROFF: Let me ask you another question. One of the things that I was a bit surprised about is the public notification. What do you do if there are potential security implications for notifying, if you have to notify potentially who may have to receive this or who's eligible for receiving this particular product under an IND?

For instance, there are security considerations in letting people know that you're using particular vaccines, let's say.

DR. CIRONE: I think that we must notify the Congress, and I think in doing that there's the possibility to do it under classified circumstances if that would become necessary.

And then I think that it would be possible that the Congress perhaps, you know, could give us guidance on the notification to the public.

And at this point I'm not an expert in that particular area. I can only tell you what the law says, but I think it probably would be possible if there's national security concerns that notice would have to be given in some form at some time, but I think they could give us guidance on how to do that.

DR. OSTROFF: You know, this issue of the anthrax post exposure prophylaxis with the vaccine is one that at least I have a little bit of concern about, I must confess. What happens if you have a situation where someone has potentially been exposed and they don't want to consent?

DR. CIRONE: A military person? I'd have to get the protocol, get the protocol approved, et cetera. My guess is that -- and this would be a guess -- is that a vaccine is given by the health care provider, and therefore, it's very possible that if that would only be informed consent. We could go to

the President; we could get a waiver of informed consent, but you know, until you have the protocol approved and you go through all of the processes and you get the waiver of informed consent, you have to assume that it's informed consent.

If it's informed consent, it's informed consent. Therefore, that member could say, "I don't want it." That's why we have to educate them. We have to tell them the pros and cons. We have to let them know the risks, et cetera, and if they determine that they don't want it, that's what informed consent is all about. We could not force it to them.

DR. DINIEGA: Ben Diniega.

Remember cipro is approved for post exposure.

DR. CIRONE: So I keep talking about --

DR. DINIEGA: You keep taking some risk in the treatment aspect or post exposure.

DR. CIRONE: But you're talking about the vaccine, correct?

DR. OSTROFF: Yes.

DR. CIRONE: Any other questions?

COL. BRADSHAW: Colonel Bradshaw.

I had one. I know there are some efforts being made to stockpile cipro, but I recently found,

and maybe someone can confirm for me, but we don't currently have cipro on the DOD formulary; is that correct?

DR. CIRONE: I believe that's correct.

COL. BRADSHAW: And I think it's because those decisions are made for other reasons that we use other, you know, fluoroquinolones, and it's a price issue and bulk purchase. But I think that makes it a little more difficult for us to have things prepositioned. It might be something we ought to look into.

LT. COL. RIDDLE: Yes. Colonel Riddle.

The way I read that directive, I mean, it applies to any force held protection measure. Let's say that I wanted to --

DR. CIRONE: Endemic diseases are included. That's correct.

LT. COL. RIDDLE: Yeah. -- that I wanted to give pre-exposure to doxycycline for a lepto risk or something for deploying forces. Even within CONUS I couldn't do that other than on a patient provider relationship. I couldn't issue guidance to do that based upon that directive.

At what level has there been a call to where that patient-provider relationship exists to

where a command surgeon -- let's say you're deploying to SOUTHCOM, wherever. Do you want to use a measure like that?

DR. CIRONE: Once again, I think that the objective was in operational environments. So if there's a deployment and there's an operational environment and it's included in DOD Directive 6200.2, then it applies.

If it's day-to-day routine within CONUS in our MTFs, medical treatment facilities, and med. centers, then I would question that that was not the intent, and if it appears that that's the intent, then it would be hampering people practicing medicine at an MTF. That should be raised and brought back, and that, I think, would have to be relooked and perhaps a change made to the directive, if you could give me the line and the paragraph, if there was a problem somewhere.

I think the intent was in deployments.

LT. COL. RIDDLE: In one of your letters, you said you -- you referenced three recommendations for the use of a particular drug. The AFEB could, in fact, make an off-label recommendation and then from a policy perspective you could reference that as a recommendation to the individual provider, that they

might want to in their patient-provider relationship use this particular drug as recommended by these expert sources.

DR. CIRONE: I would certainly hope so. We certainly appreciate the work that the AFEB did, and we are using that letter to the maximum that we can to get as many things approved and to get as many of the drug companies to support our efforts as we can.

Yes, sir.

ADM. HART: Now, is there some additional hurdle here? If we're going to seek utilization of certain medications post prophylaxis or post exposure, what is the requirement for the diagnosis?

In many cases of a biological agent, if you don't act presumptively, you're too late once you get a confirmed diagnosis.

DR. CIRONE: It depends on the label, sir. Ciprofloxacin is labeled for post exposure prophylaxis and for treatment. What is post exposure prophylaxis? In the label it says "suspected," and now how definitive is "suspected"?

I'm not going to press that issue. Maybe you want to.

ADM. HART: Nor are we.

(Laughter.)

DR. CIRONE: I don't want to press that issue.

Yes.

GEN. CLAYPOOL: I have a question, sort of a time-motion question. When you did the exercise in Virginia, I'm just curious. Is there a problem with the request coming from the CINC up to the Chairman of the Joint Chiefs to the SECDEF in order to go ahead and approve the execution of the IND in terms of what kind of a time period that takes?

I mean, I assume what's happened is the protocol has been approved. The waiver of the 18 criteria have been met. The request has gone to the President to waive the informed consent. And then it sits there until it's requested upon by a CINC.

And then once that happens, then I guess the thing could be executed. So are there time-motion things that are a problem with that? Because you may not have a lot of time to discuss that.

DR. CIRONE: We hope not. If you remember, sir, when you were my boss, we did get a request, and we brought everybody in, and then we had a video teleconference with the CINC, and we worked rather expeditiously at that particular time.

The CINCs are concerned about that. They've asked us to see if we can come up with some templates that will push this thing through, and this working group that Colonel Schnelle is addressing, once we finish the implementation plans, we're going to try to see if we can get a template so that all of this stuff is done, so that somebody can have a book, pull the book off the shelf and tell you exactly what the letter is going to look like, and we're working along those lines.

DR. DINIEGA: I have a couple. There are two things that would come up. One is requesting permission to implement an IND in the theater, which is one issue, and I think that an IND is already in place in a written OP plan. The request that would come up through the SECDEF, that would be easy to get through if everything else is in place.

A little more difficult would be an IND is in place, to get permission to implement the IND, but they want a waiver of consent. Then it triggers a whole different series of requirements, and one of the chief ones is they have to somehow verify and convince the SECDEF that the threat is real and essentially imminent or a very real threat in the theater because the SECDEF has to go forward with that information

along with the fact that we already have a preapproved FDA, approved IND.

DR. CIRONE: And, again, that is a question. What level of threat will they accept? At this point we don't know, and we hope this working group can work through that, work with other agencies outside of DOD, find out what is an acceptable level of threat.

Is it the commander's threat list, the Chairman's threat list? Is that sufficient?

At this point we don't know. I mean, we haven't had to play this and do this, and I don't know what the President of the United States and his staff would accept.

DR. OSTROFF: Sal, I think one thing that I mentioned to you earlier, but just to let the group know, I mean, we are grappling with a whole array of IND and IDE, investigational device exemption, issues at CDC right now on the basis of what happened last week, and in order to expedite things since FDA is one of our sister agencies, we've decided we can circumvent a lot of the problems by having them actually write them themselves.

DR. CIRONE: I appreciate that, and our dealings with Bayer and any other companies that want

to go off line, we've also invited CDC to join us in any meetings we have, and they've indicated that they would do that.

Thank you.

DR. BERG: Bill Berg.

Sal, do you have any indication of how the FDA feels about this?

You know, historically it can take a long time to get the protocol approved, and there may be things in a conventional protocol that may not be relevant to this. Does the FDA see the need for this and are they willing to work expeditiously and keep things to the bare minimum?

DR. CIRONE: I can't answer for the FDA, but I can say that I think the PIs, as they work the studies trying to go forward for licensure on a regular basis, work with the FDA, and our hope is that that will happen.

And if ciprofloxacin is an example, I was very pleased to see that ciprofloxacin or Bayer requested to get it approved for prophylaxis and treatment of anthrax. It was not on their label. It was on the doxycycline label.

They went to the FDA. The FDA worked very expeditiously to get that approval, and I hope that's

an indication of the future, but that's the best I can answer you.

DR. BERG: One of the things that concerns me is that anthrax is a little bit of an exception in that this had been targeted for many years. USAMRID had been working on it. They had been working with cipro.

You know, we may not be in the same position, for example, with cipro and tularemia.

DR. CIRONE: That's correct, and they may come back, and they may say, "We want additional studies," because I Don't think we have the amount of studies in tularemia or plague that we do have, and that's a concern.

And then who does the studies? Who pays for the studies? I think it will be Department of Defense, but that's not for me. I mean, there's a whole process for how you determine defense priorities.

DR. OSTROFF: Other questions?

(No response.)

DR. OSTROFF: General Peake, did you want to make other comments concerning the overall response to last week's situation in terms of the Pentagon specifically or any other aspects?

LTG. PEAKE: Well, except to say that, you know, in some ways it's sort of a multi-simultaneous phased operation right now. One is trying to get some sense of normalcy, getting people back to work, recognizing that we've got a big chunk of the Pentagon that we don't have office space in anymore, and putting people in other locations, dealing with the emotional issues which are significant, you know, in this environment, and trying to establish basically a long-term approach to that so that we take advantage of the lessons learned in previous experiences.

At the same time, looking at our responsibility for military support to civil authorities and the New York and the Pennsylvania sites, and we have some degree of support there. It is really pushing us to work through the national disaster response plan, and that is working better.

I happen to be the senior medical guy for the Hurricane Andrew experience, you know, and nobody even knew what the plan was back then. It had been published the April before.

Well, I think it's encouraging to me that there is an understanding of how that system works and how our organizations -- I think there's always that friction. Everybody wants to be involved and so

forth, but I think we're really working through that well.

And then the third piece of it is sort of this notion of trying to get our whole mindset around the campaign to rid this world of terrorism, which is a different thing again. So there's sort of three different focus areas going on with us right now, and it's pretty busy and pretty stressful for a number of folks.

I think you'd be pleased to know the focus. I mean you've heard it already a couple of times about the focus on the mental health, the understanding that it is something that we need to deal with and not push under the table and it's not macho and hoo-wa (phonetic) and all that stuff. It's let's deal with it and the senior leadership understands that stuff.

I think you'd be pleased with that. It's some of those things that are the right things. The notion and the interest in how do we protect our soldiers is something, again, that has been sort of presaged by the work that this group has done over many, many years.

So I guess that nobody is thinking this is a short term deal right now, and I think our whole

nation needs to come to grips with that. We're pretty good at kind of wham, bam, and move on. This is going to be something longer term than that, I think, and so we'll continue the engagement.

DR. OSTROFF: Let me ask Admiral Hufstader if he has any comments to make from the Marine perspective.

RADM. HUFSTADER: Well, I'd just echo what General Peake said. It's interesting to me, too, to see the evolution of awareness and psychological impact of these kinds of events and the responsiveness not just to ourselves, the medical component, but of the line commanders.

They recognize that this is a significant effectiveness detractor, and that they can have an impact on it and are quite willing to play. It's good to see that.

DR. OSTROFF: Let me turn -- Admiral Hart, any comments?

ADM. HART: I had talked to Sal a couple of weeks ago, and in our discussion realized that he was going to talk about this IND off-label use of things. Maybe medicine has had a frustrating time trying to give guidance to our hospital COs. We've written some guides on preparation and response to

bioterrorism, preparation and response to chem., preparation and response to nuclear, and as a hospital commanding officer, I like reading theory and general guidance, but I want to know what to do.

And we had to be very careful in how to craft the advice about when you suspect a bio. event. When you've got people starting to die in the ER, what action can you take?

And we come up kind of hollow because we all here know that there are effective medications just like Colonel Eng's presentation this morning, but you can't advise that.

So I appreciate the involvement of this Board, and I think that frustration is not lost on anyone here. I don't know how we're going to get there from here, but the more we learn about what's effective, the more frustrating it becomes that we can't allow decisions to be made by the commander and the medical experts on site to employ these.

So I guess I take solace in I'm not alone in this frustration, but I'm not so sure we're going to get forward very fast.

DR. OSTROFF: Thank you.

Before we take a break, Dr. Zimble has joined us. I wonder if you have any comments before

the break.

DR. ZIMBLE: Just to echo what others have said. It's been an interesting week, and I think the response by military medicine has been superb.

By some sort of fortuitous serendipity there had been planning processes going on very shortly before the event that allowed -- you know, the plan is never right, but the planning is always very important, and the fact that planning had gone on allowed people to respond very quickly to the disaster.

It's now a question, as Army Surgeon General states, of looking at these several aspects that are going on. Psychological aspects is big time stuff. The Chairman of our Department of Psychiatry, Dr. Bob Ursano, is also the chairman of a subcommittee of the APA that deals with traumatic stress, and a lot of the news media had been in touch with us the same day as the catastrophe, and he had been giving out information regarding what you tell children, how families are to react to the psychological problems.

SPRINT teams have been established by Navy. Army has psychological teams in place. There's going to be hopefully a good epidemiological study of the Pentagon regarding what went on there, and I think

we can learn some new pieces of information regarding this specific type of disaster on the home front.

So I'm looking forward to what we're going to learn from this so that we'll be even better prepared next time around.

DR. OSTROFF: Thank you.

Let me just ask if there are any questions. Ken.

CAPT. SCHOR: Just to back up the issue of applying epidemiology to combat stress, one of the things is I've worked with the SPRINT team, Don, that's working with OPNAV in our building, is how do you know that you've gotten everybody that needs to be talked to.

They've got senior leadership, three star level, four star level, and they've got inundated. We established that link within 24 hours and got leadership approval, and they're getting flooded with there's a group of 125; there's a group of 60; there's a group of this.

And then you say, "Well, how do you know you're effective?" Measures of effectiveness are always critical to figure out when to ratchet back on the full-time engagement and then kind of schedule it out.

One of the thing that we did was I was able to get my hands on the battle damage assessment of the Pentagon, and we're going to overlay the OPNAV N codes or G codes or J codes, those of you that know the lingo, over top of that battle damage assessment and then seek out those codes and make sure that those folks know that the SPRINT team is available and that they're reached.

We've hit the high exposure dose folks pretty heavily already, but we're not sure we've gotten everybody, and so it's an interesting application of an outbreak investigation model.

LTG. PEAKE: Just to make a comment about that, the Army Surgeon General's officers are outside the Pentagon actually, or we have one office in the Pentagon, but most of it is outside, and I assembled all of our people, and we were talking about it.

And, you know, the civilian work force works in the Pentagon for 30 years, and they float back and forth in different jobs, in different sections and move through the GS system, and they all know each other. And they all -- every one of them in there had somebody that they knew in the Pentagon.

So even though we're outside, you know, that's a group that would have otherwise been missed.

You say wait a minute. We've got to reach out and look.

So we're sort of the executive agent of the De Lorenzo Clinic right now, and so let's with the lead agent in this area look at all of Northern Virginia and the national Capitol region as our incident area, not just the Pentagon.

So Dewitt, you know, they're engaged out there. It's where a lot of families live that otherwise wouldn't have access. All of these new places where officers are springing up because the old place is gone are people that are high risk.

So we're trying to lay out the grid and the matrix to insure that whichever team it is is coordinated so that we don't miss people for just the reasons you said.

The other thing, as we pull in the issues here, where we're going to see even a larger incidence of people seeking assistance will be about two or three months from now. So we're starting to say what do we need to do to beef up the assets that are available two to three months from now and kind of think as a long-term campaign plan as opposed to getting caught with thinking everything is okay, and then all of a sudden start seeing the consequences.

So as Jim said, I think we will learn something from this, but I think we've already learned a lot from other experiences that we really need to apply.

DR. OSTROFF: Phil.

DR. LANDRIGAN: Phil Landrigan here.

Just let me say there's one more dimension to the epidemiologic follow-up that we've been dealing with in New York, which is where I'm from, and that's the issue of the occupational health of the workers that are going to be in there, those that have already been in there, of course, too, and the rescue and recovery and those who are going to be in there starting now already and continuing for the next many months removing the materials.

And we know, for example, in the World Trade Center that there was asbestos up to the 40th story of one of the two towers. I'm sure you must have asbestos in the Pentagon.

There may have been toxic combustion products formed during the fires when vinyl burned, for example. There may have been dioxin. We've been in touch with Steve's counterparts at CDC to get some assays done for that, and the first priority then is going to be as best we can put together a roster, a

denominator of the work force, that it won't be complete because some of the volunteers have already disbursed, but we'll do as good a job as we can of putting together such a roster. We'll do what we can to establish baseline health status indicators on them, including, I hope, mental health, and then there'll be a basis for following these men and women forward.

And up in New York when we've got such a concentration of medical schools, it will be a collaborative effort among the schools and the various actors of government. It seems reasonable to me that maybe we ought to be in touch with the folks who are putting together such a cohort at the Pentagon to the extent that the survey data instruments can be similar. That will be to the good.

LTG. PEAKE: The Center for Health and Promotion of Preventive Medicine is going to be the lead. Dr. Clinton talked to me about that today because I guess there are some people already up in New York, a few; you don't need much of our help frankly, as bet I can tell.

But we've had air sample collectors in from the very first day because I just knew we were going to have those kind of questions asked, and

briefed 633 samples from all the various corridors as far as the FBI will let us in and as far as in and on all the floors.

So far everything has been within OSHA standards. We found some lead, not aerosolized, but on the whites, and so we're making sure we're doing the wet cleaning to try to mitigate that.

But that's gone a long way to reassure people so far, and we are going to continue that sampling. You know, the concern of people being afraid to come back anyway, and then sort of the notion of, well, maybe this is a sick building; we want to be able to alleviate that very quickly with some science behind it.

So I appreciate your point.

DR. LANDRIGAN: That's all very reassuring. One of the things that we've learned over the years from the issue of asbestos in building is that it's important to have the air samples, but it's also important to complement those with having bulk samples of whatever is the source material from which the aerosol is generated. So in this instance the source material is probably the dust that people are going to be kicking up as they do their work.

And the reason it's important to get both

and to have multiple samples of both has to do with the fact that the release of material into the air is intermittent.

So it's absolutely reassuring that the air samples are below OSHA standards, but at the same time from the perspective of putting together a rational prevention plan that takes note of the various hazards that are present on site, you need to have the source samples as well.

LTG. PEAKE: The other thing that is sort of good is this is the wedge that had already been renovated, and so many of the asbestos issues had been mitigated as part of the renovation. So maybe we lucked out in terms of that to some degree, but we will take that comment and pursue it.

COL BRADSHAW: Yeah, this is Colonel Bradshaw.

I just wanted to mention from the Air Force point of view that we have been in touch through General Martinez, through General Murray, my boss, and are working with the CHPPM folks on the self-reporting and follow-up of the individuals. Dr. Ursano, as Admiral Zimble mentioned, has also been in touch with the CHPPM folks and is actively involved.

And I should mention that we've done a

Cobar Towers investigation in the Air Force, along with the folks who did the Oklahoma City Murrah Federal Building follow-up. The Oklahoma epidemiologists there and Tim Davis at the CDC, CHPPM has already ben in touch with him.

So if you guys are anticipating that sort of thing I'm sure that Colonel Eggerton at CHPPM and others that will all be glad to try and be on the same sheet of music in terms of what we're doing. They're looking at both injury follow-up and some, you know, PTSD and other types of mental health questions, et cetera, et cetera.

So I think collaboration and coordination is certainly important in this, and as we mentioned, they also did an environmental survey.

DR. OSTROFF: General Peake, I think you have to go.

LTG. PEAKE: I have to go. Actually I'm going up to Dover and then to CHMP later on today.

So again, my thanks for letting me come visit with you, and I appreciate what you're doing.

DR. OSTROFF: Thanks. We appreciate your being here.

Why don't we go ahead and take our break now. We're a couple of minutes ahead of schedule, and

we have a 15 minute break scheduled, and let's try to come back at ten after.

(Whereupon, the foregoing matter went off the record at 10:55 a.m. and went back on the record at 11:25 a.m.)

DR. OSTROFF: We have Lieutenant Colonel Art Baker, the Reportable Diseases Project Officer who's going to give us an overview of tri-service reportable medical events.

And I must confess I read this quite closely last evening. So I'll be interested in your presentation.

(Laughter.)

LtCOL. BAKER: Thank you very much.

I'm Art Baker, and I'm going to talk about the tri-service report and medical events.

I want to divide this presentation into five areas. I want to give you a background on it. I want to talk about the tri-service reportable event list, the criteria for inclusion and exclusion, guidelines for reporting.

And then I wanted also to talk about the data flow of the reportable medical events from each of the services into the defense medical surveillance system.

Finally, I'd like to give a summary of some of the reportable event data and discuss the completeness of the reportable events.

Now, to give you some background on the tri-service reportable events, in December of 1997, there was a meeting and a consensus was arrived at amongst the services on what events were reportable. By July of 1998 a case definition document had been compiled and distributed to the various individuals for comment, and then it was finally published.

By January of 2000, all of the services, Army, Navy, Air Force and the Marines through other services were reporting medical events on a relatively consistent basis, and by January of 2001, we had reconvened and looked at the reportable event list to see whether or not there were any changes that needed to be done either in the specific conditions to be listed or in the terms or the conditions for which that individual event would be reported.

This is a picture of the tri-service reportable events. This is the cover. It has all of the guidelines and case definitions in it, and this is something that's available on the Internet. You can download it and read through it, and if you have any comments, I'd be happy to have you send me an E-mail

about that.

And this is available at the AMSA Web page, amsa.army.mil.

Now, we used some very specific criteria for deciding what kind of event should be included in the tri-service reportable events. First of all, we wanted to include events for which there was no other timely source of data available, and timely for us was anyplace from a couple of days to a month.

We wanted to have a very clear case definition available so that there wouldn't be any struggle over what to include and what not to include.

We wanted to have an ICD-9 code for each of the conditions so that we could more accurately group and do statistical analysis on the events that were reported.

We also wanted to make sure that there was an intervention available for each of the conditions that were going to be reported and that this kind of intervention would be important because of the high degree of public health impact that this condition would have.

And also, it would help us to identify failures in the preventive medicine infrastructure locally whenever we didn't see events being reported

that were elsewhere reported.

We also included as criteria for medical event inclusion the urgency of the condition, its potential for affecting large populations of people, the clinical severity associated with the medical condition, the ease of transmissibility, and finally the potential for severe mission compromise.

Most importantly, we also looked at events that were mandated by outside agencies, such as the CDC and state, and finally, we wanted to look at events, include events that were militarily unique threats.

And although you won't be able to read this slide form any place in the room unless you're standing next to me, these are all of the events. This is also available on the Internet from that book that you can download if you wish.

Now, you can see on here that we have really exotic conditions that have never been reported before, such as we haven't had any anthrax cases reported. We haven't had any biologic warfare agent exposures, but you can see that these conditions meet some of the criteria for which we included them in this list.

Other conditions are of great

significance. For example, down here in the malaria area -- let me just see if I've got this done right. Yeah, right down here in the malaria area we're very interested in these, and we actually get as soon as a case is diagnosed anyplace in the military treatment system of any service -- these usually come to us pretty quickly.

Now, this is a sample page that's probably difficult to read from your position, but let me tell you that this is a sample page out of our manual, and we organize every condition under these kinds of headings.

For example -- oops, sorry. Got to go back two. Yeah, right here. Good. Thank you. And I've got this took here.

First of all, we give a clinical description of the condition. We've actually selected Dengue fever here. We give a clinical description.

Next we give a clinical case definition. We give a -- further down we give the laboratory diagnosis or criteria for diagnosis, and we give a case classification here. Any further requiring comments and additional considerations, and we do this for every case so that when people are wondering, "Should I report this case of Rocky Mountain spotted

fever with an IgG titer of one to 64?" no, I don't think so.

But we provide this so that there will be continuity and consistency of reporting.

Now, I want to tell you how the tri-service reportable events fit into the DMSS, and I need to give you a kind of an architecture or a functional organizational.

The defense medical surveillance system has data that comes into it. It has personnel data. It has medical data. It has serologic data, and it has deployment data, and all of these columns feed into the defense medical surveillance system.

Now, specifically, we receive reportable medical events from the Army, Navy, and Air Force which also come into the defense medical surveillance system, and this information then is used to generate various kinds of reports: the medical surveillance monthly report. We have ad hoc requests for persons who have particular requests about the data.

We do studies and analysis, and then we have routine reports and summaries that are produced from this database.

In addition, this database can be queried through the Internet with DMED, which is a remote

access front end to the DMS database, and you can look at reportable events with DMED, reportable events that are in DMSS.

Now, the tri-service reports come into DMSS from different services. There's the Army system, which is called RMES. There is the Navy-Marine Corps system of reporting tri-service reportable events, which is the NDRS. And then there is the Air Force system called the AFRES.

These events are located or found or identified by providers who are in medical treatment facilities. They're in clinics. They're in ships. Sometimes they're in battalion aid stations, and these events then get reported up to the reporting sites that they're associated with.

And these reporting sites in the case of the Army are at 34 different reporting sites. In the case of the Navy, there are four ENPUs, and there are 79 -- there are approximately 70 reporting sites for the Air Force, and these reports that are generated at each service level come up to their respective service surveillance centers, and each of these respective service surveillance centers send their reports into DMSS.

These reports are also standardized and

they have characteristics that make them manageable in a database upon which statistical analysis can be done. For example, each case is ICD-9 based. Each case has a unique case number so that a case number in the Air Force will never be found in the Army case number series or in the Navy case number series.

There are a minimal number of essential data elements, and we'll look at these on another slide, what the specific data elements are.

There is a comment field available to describe the case in the event that the individual reporting the case feels like they need to add a little bit more information.

We require that there be an indication of whether or not the case is confirmed, and the reason -- and we also want to know the method of confirmation. Was this a clinical case? Was this confirmed by serology or by slide, for example, with malaria, or what was the technique? And there are selected techniques that can be chosen.

If there is not a confirmation of this case, then it's not included in any of our analysis. Now, these are the data elements that we request for each case, and it's broken up basically into two groups: the demographic data, as well as the medical

data.

This helps us to sort cases by demographics and let me just -- this is the case number. This is the DMISID. This is a unique number assigned each medical treatment facility, first name, last name, family member prefix, Social Security number, patient category, race/ethnicity, sex, date of birth, and grade.

These are the medical data, and you can see diagnosis, date of onset, and for some disease, we want to know about whether or not the disease was confirmed and what the method of confirmation was, and we provide these other data fields. And these are all described in the tri-service manual.

Now I'd like to turn for a moment and look at the number of cases that have been reported by the different services to DMSS, and these are on active duty service members, cases that have been reported on active duty service members between 1995 and 2000.

the Army started reporting cases in '95 and '96, and then there was an effort made to give feedback to the field about the quality of the case, whether or not it was confirmed, and that kind of feedback.

And as a result, we had a step up in the

number of cases, and we were generally above the 8,000 line and here in this 2,000 year, we were over 95 -- about 9,500.

The Navy has also transmitted cases, and you'll see that there is a declining value here on the number of cases that the Navy sends to us, and one of the reasons that we suspect that this is true is that there is a long lag time between the time a case is actually identified at a naval site and then finally gets through their system of transmission and to DMSS through the tri-service reporting system.

You can see that the light beige color here is the Air Force, and over time it has increased in the number of cases, and this actually reflects, I think, an attention that the Air Force has paid to the reporting system in an effort to get their multiple reporting sites to send their cases in on a more timely basis.

We'll go on to the next one.

Now, these are the 15 most commonly reported cases so far in the DMSS, and this is for 1998, '99, and 2000, and you can see that the most common diagnosis and the most common cases are sexually transmitted diseases.

So that in 1998, 55 percent of all the

cases reported in 1998 were chlamydia cases, in 1997, 57 percent, and in 2000 it was 65 percent. All of the cases so far in these three years that have been reported for chlamydia, there were 20,000 cases of chlamydia.

You can see it drops down quickly to gonorrhea, non-gonococcal urethritis, it's small, and then the leading cause of -- the leading report is our heat injuries.

We stopped at 15 because this was the first set where the percentage was less than zero, and you can see that over three years there were 106 cases of Hepatitis C reported through the tri-service reportable event system.

Now, as you know, surveillance systems are measured usually in two kinds of measures. One is timeliness, and we're not going to talk about timeliness today, but the other issue is by completeness, and we define completeness as being based on the percentage -- on the percent of all hospitalizations that are required to be reported that were actually reported to DMSS and the total number of hospitalizations for services based on the standard in-patient data records so that we actually get all of the -- we know all of the cases, all of the

hospitalized cases in all of the services, and then we look through all of those hospitalized cases and say, "Now, which one of these should have been required to be reported through the tri-service system?"

And then we go to each service and say, "Now, of these cases that should have been reported, how many of them did you report?"

And that percentage is used to establish the completeness of reporting. This completeness is only based on active duty admissions to military treatment facilities. So we don't include soldiers who get into a car accident on the interstate and they're dragged off to the nearest civilian facility. We only count cases that were hospitalized in military medical treatment facilities.

So that if we look at completeness of reporting of required reportable hospitalizations amongst active duty service members in this time frame, you can see that the Army started out here at about 30 percent back in '95, and in this time frame, there began to be more feedback to the reporting sites saying, "We need this information. We need it in a more timely manner, and why couldn't you also tell us about these?"

And helped to tune up the reporting sites

and so that we're -- about 60 percent of the required reports are actually reported. Now, some people think that 60 percent is is not a very good number. Actually if you look at other active surveillance systems, if you get ten or 15 percent of cases, that's pretty darn good. So that the Army is actually maybe four times better than what you usually expect.

Now, in about '98, the Air Force and the Navy started adding cases, and you can see that the Air Force has begun to implement reporting of cases and also a new system so that they're moving up from ten to 30 percent, and I think that you can see that the Navy has basically remained around 15 percent, and this is probably again due to the lag time that's associated with bringing cases in.

Okay. That concludes my briefing. Are there any questions I may answer?

DR. OSTROFF: Oh, yes.

(Laughter.)

DR. OSTROFF: Let me start by thanking you for the presentation and thanking you for at least making an attempt to bring some structure out of what to me when I first started dealing with this five or six years ago looked incredibly chaotic with no consistent case definitions and no consistent ways of

reporting and no standardized list of diseases, et cetera, et cetera, et cetera.

But I guess my initial question to you is to what degree does this really reflect reality, and the reason I ask that is that while 60 percent from the Army may look pretty good if what you're measuring is hospitalizations, for the vast majority of these, these people don't get hospitalized.

LtCOL. BAKER: Exactly.

DR. OSTROFF: So when you compare them to surveillance systems that are picking up ten or 15 percent, you're talking about surveillance systems where most of this is being diagnosed on an out-patient setting.

LtCOL. BAKER: Right.

DR. OSTROFF: So I'm not sure that's a fair comparison.

LtCOL. BAKER: You're exactly right. It is a surrogate measure, and it's not the best surrogate measure, but I don't think that a better one can be easily found that can be used as a standard.

The other value of having this as a measure is that it provides an opportunity to talk to the services or the actual reporting sites about, well, how do you go about identifying cases and to

say, well, you know, you can go to your PAD, your Patient Administration Division, and say, "I need to know all the patients that were discharged with these ICD-9 codes because I have to report it to the tri-service thing. And, by the way, I need to know all of the patients who had laboratory values that were these kind of serologic results because I need to report them to the tri-service."

So what it does in a way it kind of stimulates the reporting sites to begin to think about how are they going to capture data, not the easy data of the patient hospitalized and discharged, but the harder data of out-patients, and those are a couple of different routes.

Part of those routes are through the laboratory system. Part of them are through the KGADS system, the ADS system for whatever value that may have at an individual site, and to begin to think of other ways of capturing data.

COL. RUBERTONE: If I could address the ambulatory data, we also get the ambulatory data int he --

DR. OSTROFF: Could you identify yourself?

COL. RUBERTONE: Sorry. Mark Rubertone at the Army Medical Surveillance Activity.

We do get the ambulatory data, and we have looked now for a number of years at the feasibility of using that to look at the completeness of reporting because we understand the surrogate measure of in-patient hospitalizations.

There's a two-fold problem. The first and main one is that there's no level of confirming a case in the ambulatory data system. So suspected cases are given the diagnosis that they may end up B or not B. So it would be hard to compare against that.

And the other and more troublesome is the accuracy of the data. Currently in the ambulatory data system, there are about 1,600 cases of anthrax that have been diagnosed.

DR. OSTROFF: Impressive.

(Laughter.)

DR. OSTROFF: You have a problem.

COL. RUBERTONE: Huge outbreak. Now, we realize that these were diagnosed at immunization clinics and very likely were or absolutely were immunizations, but that's just one example of how we would be really finding fault with the reporting sites on their completeness of reporting when it may not be true.

And even though 60 percent, I think, is

also good, we're held to a very high standard in the military, and that has three digits: 100 percent reporting. So they really want all sites to have 100 percent reporting, and if you compare, if your gold standard is tarnished, then you have a little bit of a problem with that.

DR. OSTROFF: Can I ask Captain Yund to comment about the delays or the lag times in data reporting?

I mean, even in the public health sector two years would seem to be a little bit on the lengthy side.

(Laughter.)

CAPT. YUND: I think that certainly there are some delays, but I don't think the delays in reporting are what are responsible for the low numbers in the Navy, and I'll let Dana comment about the Air Force.

I think that what's responsible for those low numbers is low, very low compliance with reporting out there with the data coming into the EPMUs.

There have been some other problems where a few breakdowns where the data has not in the past always gotten forwarded past NEHC, and there have been a number of things that I thought were being

worked on or being fixed, but this obviously showing that we haven't identified -- we haven't fixed the problem, but I don't think it's delay. I think it's a compliance issue.

DR. OSTROFF: Dr. Berg.

DR. BERG: Yeah, I thought Colonel Baker was being a bit diplomatic when he described it as a delay. Sine we have Captain Bohnker here who is from NEHC, I would wonder whether he might be willing to say a few words as to what NEHC hopes to do to improve this process.

(Laughter.)

CAPT. BOHNKER: I don't know that I would speak for NEHC. I can tell you what I've been working on. A great thing; been there two months. You can understand that.

(Laughter.)

CAPT. BOHNKER: What would you like to hear about? Y2K? Would like to hear about the INFOSEC problem with the zip files which are being deleted from our processing system as they bring it up from the ships in the EPMUs, which creates -- which deletes the data?

There's lots of information, lots of problems there that we're working on right now, and I

can't tell you how to solve it. I'd be happy to bring it back and give you a presentation next time on that whole topic if you'd like. A fascinating area.

We have the same top three in terms 'of chlamydia, gonorrhea, and NSU, is our top three. Our numbers actually -- I think it's actually a Y2K issue, why it went down in 2000 because it came back up in 2001. We had to get the computer program Y2K compliant to be able to use it on the ships.

There's a couple of issues that really bring this problem because in the Navy we have to be able to run our system on ships with 200 people on it and a first class petty officer. Okay? Just like Bethesda Navy Hospital, in order to make it work in the Navy, it's got to be a first class petty officer on a frigate in the middle of the ocean, and he has all of the capability in terms of medical departments. Bethesda does, and he has individual reporting requirements that comes from him to the EPMUs and on up to there.

We drive a lot of our system that way. We still have some big issues in reporting we get to work on, and we're working on them, a fascinating area.

DR. OSTROFF: Let me go this side first.

DR. HERBOLD: John Herbold.

If you could help clarify part of this for me, on the hospitalization data, it's a matter of timeliness versus completeness because my understanding is that eventually all of the discharge diagnoses are gathered somewhere.

LtCOL. BAKER: Yes, they are.

DR. HERBOLD: So the hospitalization data, it's a matter -- it's how soon you find out about it so that you can do something about it rather than having to wait a year to get the tapes.

LtCOL. BAKER: Right. Let me see if I can answer this. Our completeness and timeliness analysis is done six months after a given period. For example, our January to June completeness reporting we will actually do in December, and it will be a look-back kind of exercise to say to the site, "You know, we've finally gotten in all of the hospitalization data. We know when the patient was hospitalized, the date of onset. We know what day you reported it, if you did report it, and now we can look back and say that of the 30 cases that you should have reported to us, you reported 20, got a 66 percent, and of those 20 that you reported to us, one portion was reported within a week of discharge. Another portion was reported within two weeks of discharge," and that kind of

cumulative percentage we can do.

So that we give a kind of assessment at the local level at the reporting site as to what they're doing, and that gives the opportunity to the preventive medicine officer to look at the processes and systems that the preventive officer has in place to determine if they're functioning.

Does that answer?

DR. HERBOLD: Well, if you can help me just a little bit because it's been like 15 years sine I've had hands on on this, the information at least for the hospitalized patient is being collected at, say, the registrar's office, and so it's captured at some point in time, and for sure it's captured by the time the patient is discharged.

LtCOL. BAKER: Correct.

DR. HERBOLD: And so the question there seems to me more it's a matter of process of how many different bean counters are going to be included in getting the information and where it's chopped to, right?

LtCOL. BAKER: Right, and the approach is for the preventive medicine officer to go down to the bean counter and say, you know, "This week can you give me a listing of all the people that had these

ICD-9 codes?"

DR. HERBOLD: And that's a solvable problem.

LtCOL. BAKER: Some places have it very easily -- have it very well handled. For example, out at Tripler, Ed Tanaguchi and Colonel Wasserman get regular reports from the PAD people through their CHCS gurus, and they enter that data, and they typically are always at 100 percent.

And other places are not able to interface as easily with their reporting systems to their PAD office, and that's part of training and educating.

DR. HERBOLD: Okay. Well, can you tell me then how the ambulatory data is collected in 2001? Is that collected electronically or is that still all paper?

COL. RUBERTONE: Both. At the clinics, in some clinics they're both. It's collected electronically. It's entered electronically, and in some places it's entered on paper.

It then goes to a central place within the hospital where it's converted into an electronic file, and my understanding is that it goes off to -- I can't remember where it's at, Mark.

DR. HERBOLD: If I could interrupt, I

think what you're talking about is it's believed that all of the ambulatory visits within the military treatment facility enterprise end up in the central ambulatory data down to the level of the troop medical clinic.

So below that level, at battalion aid stations, aboard some ships even in deployed situations, we don't get that data electronically. It remains as a paper based record. I think that's what your question was.

But above the troop medical clinic, we do get that data, and are you asking why there's a redundant system, why we have a reportable event system if we have these other electronic methods of receiving data?

DR. HERBOLD: Well, one thing is if you're capturing it in the hospital setting electronically, yes, I'm asking why can't that be disbursed where it needs to go.

COL. RUBERTON: It's timeliness. Right now on average our in-patient data record takes approximately three to four months before we see it in the defense medical surveillance system at a central surveillance location, and that's because the chart has to be reviewed by a nosologist. It has to be

signed off by the health care provider.

It then churns through the system. Most of these systems kind of work on a monthly basis. I will say that there's efforts to improve that, and I do feel that in the near future that will be down to maybe within 30 days we'll hear about it and maybe even very timely the next day or so.

When that occurs, we can do away with a reportable event system because there's really no reason to have that redundancy, but right now it's timeliness.

We hear about cases of malaria in Korea the day after they happen, whereas if there was a hospitalized case, it would take three or four months for us to hear about it otherwise.

DR. OSTROFF: Time is running dear. Let's just take two more quick questions, and then we'll move on to the very important conflict of interest training so that we can then go to lunch.

DR. SHANAHAN: Okay. Dennis Shanahan.

One question I had is I notice on injury that you're collecting only environmental exposure. I'd like to know why you excluded other forms of injury.

And the second question I really have is

related to bias in your relatively slow sampling rate. For instance, it's very clear that your top three are not based upon hospital data, that you are getting a certain amount of ambulatory data in there as well, but it's clear to me that there's a lot of selection bias going on in what you're getting and how you deal with that.

LtCOL. BAKER: I'm not sure that -- let's see. How do we deal with selection bias?

Well, it is what we have, and we try to enhance completeness of reporting, and I'm not sure how to answer that.

DR. SHANAHAN: Well, basically my point is how do we know that we're not just seeing the tip of the iceberg in your first three.

LtCOL. BAKER: We are.

COL. RUBERTONE: Right. We don't know that definitively. We can look at the ambulatory data record and say how many cases of chlamydia were diagnosed, and we have done that. And in some cases, some locations the compliance is actually greater than 60 percent of what we see, and those tend to be the cases such as Madigan and Fort Bragg where they have centralized STD clinics, and they have very good reporting.

In other places it's much lower than 60 percent because it is more decentralized in how it's treated.

So you're right. In terms of the completeness reporting, we use the in-patient data as a surrogate. It's our best measure, and we feel that that if nothing else has improved upon the reporting of even out-patient conditions because you can see how the number of reports have increased.

On your first question, which was -- which is escaping me now.

DR. SHANAHAN: Traumatic versus --

COL. RUBERTONE: Right. That was not an easy decision, but a lot of it came down with the criteria for including the different conditions as to was this something that was truly preventable. Was it something that the preventive medicine communities in the services had visibility to?

You know, if you want to make carpel tunnel syndrome reportable, you've burdened the PRIM-S (phonetic) and the occupational health clinics with a lot more effort to gather all of that data from the different sources in order to report it.

So the services more or less went with the communicable disease model with some other military

important diseases, the heat and cold injuries.

DR. OSTROFF: Dana, very quick, and then Dr. Zimble, and then we'll go on.

COL. BRADSHAW: I'll try and be quick if I can, but I'm trying to go back and catch a lot of things.

There an IOIPC, which has been presented here, that's working on injury issues, but there's also the safety community where we have an epidemiologist in the Air Force at our safety community, and they at least get reported there.

And then disease, non-battle injuries are included in several categories there, including MVAs, et cetera, et cetera. I just wanted to speak quickly to the Air Force issues and some of the global issues about reporting.

As everyone is aware, passive reporting systems, which these are, are very sensitive to the emphasis that's placed on them. I think the Army has done a very good job at emphasizing and doing a lot of feedback to the field and putting a lot of emphasis on their reporting. And I think that's largely why I think they're getting, you know, good reporting rates.

In the Air Force, I've kind of felt convinced because of some of the problems that have

been discussed here that we want to go to as much as possible for those for which it applies doing active laboratory based surveillance so that we kind of skip the human factors in between if we can, and then get to a better data set.

But there are some other problems with that, and when I got to GEIS, that's one of the things I want to try and follow-up on, and I know Joel and them have already been working on that.

Some of the issues about the Air Force reportable incidence surveillance system and where we are, and Mark can confirm this, but I know part of the problem with our system, part of it is lack of emphasis, but secondarily it was also that I think when we changed over to the agreed upon data set, that one of the requirements, for instance, confirmable reportable event, that we weren't doing that good a job at getting the confirmable.

And so then it doesn't show up. So if you don't confirm it, then it doesn't go into that, you know, reporting set. So a lot of that rise, I think, has been FIERA (phonetic), trying to get the confirmable and some other issues taken care of, and so that's part of where we're coming from, I think, on the Air Force side.

Lastly, there are some things that clearly, like the sexually transmitted disease, our clinicians remember and they report fairly well. I presented earlier in February, I guess, of this year about chlamydia for the Air Force, and about two thirds or even up to 70 percent of our chlamydia we can match to a laboratory test.

So some of those things we do pretty good on, but if it's shigella, if I remember a couple or three years ago when I was at DMSS, maybe one percent got reported. So obviously we've got problems elsewhere.

DR. OSTROFF: Very quick, Dr. Zimble.

DR. ZIMBLE: Yeah. I would just like to say that, first of all, I want to compliment you for what you've done. I was fleet surgeon in the Atlantic Fleet in 1983 to 1986 when there was nothing, and there was no way I could advise my CINC on any kind of intervention because I didn't know what to intervene with.

So something has happened, but it really is a systems problem, and it's an unstable environment. The platforms move. The people move. Keeping them educated and maintaining a discipline for reporting is a very Herculean task, and what we need

is to urge Department of Defense to get on with what Dr. DeBlanck had been advertising for years, is the PIC.

If we get to the point where there's a chip that every serviceman wears and data gets entered onto that and that data gets entered into the system, then it's part of the routine business of taking care of the troops that's going to get the information delivered, and the feedback is essential. If there's not good, adequate, fast feedback, it's meaningless.

And I'm delighted to see that you have a report. I don't know how many people read it. I don't know how much they can get out of it. If you can't regionalize the data, then it comes back.

But this may not be much, but it's a lot compared to what things were like 20 years ago.

DR. OSTROFF: I agree. Thank you for the presentation.

DR. ZIMBLE: You're welcome.

DR. OSTROFF: Let me just point out for the Board that Colonel Gibson's presentation concerning JP-8 because of the changes in the schedule we won't have time for, but the handout is in the briefing materials.

We're going to move on to Mr. Criss from

the Army JAG Office to do the conflict of interest.

MR. CRISS: Well, I'm Charlie Criss with the Army Standards of Conduct Office, and I'm an ethics attorney.

And you presented me a real challenge, an attorney presenting this topic in about a minus two minutes, but --

DR. OSTROFF: No. We're not hungry yet.

(Laughter.)

MR. CRISS: I can do this mission.

DR. OSTROFF: And his material was in Tab 4 in your notebook.

MR. CRISS: It is in Tab 4, and there's a couple of high speed outlines in Tab 4. So actually if I don't say anything and you would look at those last two outlines and study those, take that home as homework, then you'd know everything that you really need to know.

But what I want to talk to you about is the one topic that would prevent you from serving on this Board, and that's conflicts of interest, and before you serve on the Board you fill out that OGE Form 450, in which you list your assets, liabilities, transactions, and things like that, and then that goes to me with a copy of your resume and what it is that

you intend to do for the Board.

And then I review that in junction with Rick, and we just kind of spot check that to see if there might be any conflicts of interest.

So if there are, then it's unlikely that you would serve on this Board. Now, there are a couple of mechanisms by which we can change things around so that if it's so important that you serve on this Board in light of that conflict of interest, then we can make that happen possibly in conjunction with the Office of Government Ethics.

But let me start at the beginning and try to be real quick. On that first outline, the first information paper, the only thing I want to point out there is that you're a little different than many of us in the room. Those who are wearing the uniform are subject to the standards of conduct for executive branch employees, and those of us who are civilians are also subject to those. But you are special government employees, and as such, you're also subject to the restrictions, but to a lesser degree.

And a special government employee is someone who is serving for the government during some 12 consecutive months, for a period of less than 130 days. So think of it as a temporary employee, and

that's what you are.

And I understand that you're all serving here gratis, more or less as a volunteer without compensation. And for that reason also you're special.

Now, I want to go into the second outline, and that's the one that really talks about conflicts of interest, actual conflicts and the appearance of conflicts.

And on the appearance of conflicts, kind of think of it as what would Joe Taxpayer in Peoria, Illinois think if you, for instance, were employed by a vaccine manufacturer and you came in here to work on a particular study in regard to a vaccine or an anthrax something or other.

The recommendation that you might make in that study in this Board, if it were to have an impact on your employment, if you were able to recommend to your fellow Board members and sway the Board that whatever the recommendation it is that you're making would have an impact on your private employment with, let's say, Eli Lilly or Pfizer, and because of that recommendation the federal government would say, "We like that. We'll go that way, and we'll award that contract for that vaccine, too, that vaccine

manufacturer," which is your employer, then not only would Joe Taxpayer in Peoria, Illinois think that there's something strange about that, but there would also be an actual conflict of interest.

So that's the kind of things we're looking at when you fill out that OGE Form 450.

The last outline is -- and this would really, I think, be the most benefit to you -- is take that outline home because it talks about when you go through that 450 line by line, here's the things you want to look at.

That will prevent rick from having to kick back -- after he sends me the OGE-450, but he's real good. He's looking at these things before he seven sends them to me, and he's catching a lot of these omissions and sending them back to you before they come to our office.

But if it comes to our office, if there's something that needs to be corrected or additional information or what did you mean by this, then I'll kick it back to Rick, and Rick will kick it back to you, and then you'll need to flesh out whatever it is that we're seeking in regard to additional information.

So that last outline that talks about

specifics concerning what goes on the OGE Form 450, I think, would be the most helpful for you.

On that second outline, that second information paper regarding -- I'm sorry. The first one that talks about what is a special government employee. If you'll change -- there's a typo on here. On those four subparagraphs, A through D, at the bottom, I think it is, that talk about 10 USC, 10 U.S. Code, change that from 10 USC to 18 USC.

Those are all criminal statutes, and Congress was concerned about anyone who has a conflict of interest, for instance, and deals in their capacity by service on this Board, for instance, with a financial interest that they or a member of this household have on the outside commits a criminal act.

And you really don't need to be explaining in a federal courtroom why your service on this Board was dealing in self-interest for what you deal in the outside. And I know that most of you are serving in academia, but we also have a couple of people, as I understand, on foundations. we even have some federal employees that serve on the Board. And for those individuals that's not a concern.

But for the rest of you who are really special government employees, it is. So --

DR. OSTROFF: Can I ask just out of ignorance --

MR. CRISS: Yes, sir.

DR. OSTROFF: -- what happened to C? It goes A, B, D, E. Was there one missing?

MR. CRISS: No, that's yet another typo that I didn't even catch. Thank you.

But those are the four subparagraphs I want you to change from 10 USC to 18 USC.

So really the two things I wanted to cover today, conflicts of interest, what they are, you'll find that in your second information paper.

And secondly, what do I really need to put down on that OGE Form 450?

And the last thing I want to say about that is Rick is having you do new 450s now , and the technical deadline for that, filing of those in the federal government is 30 November. But if you can have those in before that, you're just ahead of the game, and that will just save everybody a lot of work.

I'm sorry I don't have more time to go into this, but are there any questions, particularly about conflicts of interest?

LT. COL. RIDDLE: I just forwarded everybody a package, and we're trying to make it just

as absolutely as easy as possible. So you should have got a form, a disk that has a fillable PDF file, and an Excel spreadsheet on it. With the Excel spreadsheet you can save your information and update it from year to year.

We're required to do it in September, at the time you're appointed in September of every year, and when you're reappointed. So you may actually have two of these in a particular year, but if you save it on that Excel spreadsheet, on that disk and we've got the information that we can fill out filled out on there, then that will make it that much easier for you to try to simplify those processes.

DR. SHANAHAN: They sent it out already?

LT. COL. RIDDLE: Yes, sent it out --

DR. LANDRIGAN: Mine just came in yesterday.

DR. SHANAHAN: Okay. Well, the mail is a little bit behind. Okay.

DR. OSTROFF: If I can just make one comment, there were several very valuable members of the Board that were extremely dedicated to Board activities, that when they were nominated and approved to be Board members were not working for pharmaceutical companies and then went into employment

with pharmaceutical companies.

And I think it was somewhat traumatic for Marc LaForce, in particular, to then have to have these individuals removed since they had provided such valuable input in terms of many of the things that we were dealing with.

I don't know. Was that something new that came up or has this always been the policy?

MR. CRISS: That preceded my time in the office. What I understand, and let me answer it this way, I understand that you're focusing on three areas: the OSHA type things, the health maintenance, and then the disease control.

And we're really most interested in the disease control of what you do and particularly the vaccine manufacturers. So it would probably be a show stopper if we would have somebody employed with one of the vaccine manufacturers that was going to serve on that disease control aspect of what the AFEB does.

Now, I've talked it over with my supervisor, and we handle the Army Science Board, for instance, a little bit differently than this, and they also fill out 450s, but it's a much larger Board, about 100 people, and they have topics that are assigned to them as you do, and I've seen some of your

reports at least on the Web site.

But whenever they are assigned a topic at the Army Science Board, we ask to see the terms of reference on that topic, and then we look at the individuals who have been asked to tackle that topic, and then we look at the 450s, and we kind of match that 450 up with the terms of reference to see if there's any conflicts of interest.

For AFEB members, my boss has said that we're really just interested in the vaccine aspect of what your business is, and in regard to that, we're really going to look at your employer.

So the 450s that I've seen with that 2292 that has been sent to me, no one has been employed by a vaccine manufacturer. So it hasn't even come up.

But I think were that to happen, what we could look at, sir, is if something occurred like that in the future. Then we would look at what we call a 208(b)(1) waiver, which in essence says that this gentleman is so important for what he knows to the defense of the nation that it's more important that the United States government mine his knowledge on that particular topic than it is that he works for that vaccine manufacturer because that vaccine manufacturer is the only one that can manufacture this

vaccine, and he's the only scientist that has the expertise that can make it happen.

So if there's something like that, it's possible to wicker a waiver up to get an exception, and in the entire Army last year, there were only three of those done. In the entire Air Force, to my knowledge, there's only one done. So it's kind of a rare animal to do one of these 208(b)(1) waivers, but it's possible, and we'd definitely look at that.

DR. OSTROFF: David?

DR. ATKINS: I'm at a federal agency, and our approach, my understanding, has been slightly different. I run a federally supported panel, and we have members -- we have one member from industry, but we view conflict of interest on a topic by topic basis, and so we haven't prohibited him from serving on the panel, but we recognize that if a specific topic comes up where his employer is involved in producing a product relevant to that, that he has a conflict of interest. He declares it. He recuses himself from votes on that.

And I'm wondering if that kind of option is possible. I think clearly we would all recognize that someone employed by Merck or the maker of Lyme disease vaccine would have a conflict when the

question is should the Army be vaccinating routinely for Lyme disease.

But their expertise could be very valuable in other infectious disease guidance where the conflict of interest is manageable.

MR. CRISS: That raises two things. I'll answer it this way. I think in that situation the appearance of the conflict would still be there, and it wouldn't -- for Joe Taxpayer, again, in Peoria, Illinois, who doesn't even recognize the difference between a Marine Corps uniform and an Army uniform, it wouldn't make any difference. This person is sitting on that panel, participating in discussions, but saying, "Well, I can't talk about it. I can't make a recommendation on that one." So I think the appearance would still be there.

The other thing is that it's still up to the individual member to recognize when the conflict is, and that appears at the bottom of the first paragraph on that what is an SGE.

It says ultimately it's up to the individual member to recognize that there might be a potential conflict of interest.

And remember we're talking criminal statutes. So you don't want to do anything that can

cross the line, cross the line into criminality and wind up in a courtroom.

So when I say it's ultimately up to you, when the situation comes forward and Rick says, "Well, let's tackle this study. Let's have this subcommittee tackle this study," and if you're involved in something on the outside or a person with whom you have a relationship, i.e., your wife or a child or a significant other, which is imputed to you -- their financial interests are imputed to you -- if you recognize that conflict of interest, then tell Rick, and Rick can say, "Let me call Charlie and see if this is going to be a problem."

But it really rests with you as to determine do I have a conflict, and what I've tried to do is point out the areas of the conflict with that information paper so that you'll see the red flag when you address that issue before the Board, and if the red flag goes up, get hold of Rick and he'll know to get hold of me, and we'll try to figure out which one of about five remedies are available to work around that.

Yes, sir.

DR. BERG: Bill Berg.

Just out of curiosity, you said there were

very few waivers. Is that because very few were requested or because there's a very high bar?

MR. CRISS: I would say, sir, because very few are requested, and when I talk about five various remedies to get around this, the most frequent that we see is just a disqualification statement which typically says, "I hold stock in General Electric, Pfizer, Merck, and Verizon, and therefore, if something comes across my desk as an official member of this Board to act on concerning any one of those entities, then I'm just not going to act on it.

So in most cases, see, we can allow that employee, having disqualified themselves from whatever it is that they've listed, to go ahead and do their federal function and let their XO or somebody else in the office handle it.

But I think it's a little tighter in regard to the AFEB because what you're going to have is a single scope study, and if you have a conflict with whatever you may own or have some interest in or your employer that conflicts with that study, then a disqualification statement, if it were to say, "Well, I'm not even going to participate in that in my official capacity," then the effect of that is that you can't serve on that study.

So a disqualification may not really be a viable avenue, and we may have to then seek the waiver, and I think you have the advantage here about being the AFEB because you are such a body of expertise that's so rare out there that you're willing to donate that expertise to the government, that a wavier in that regard may be for this body a remedy that we may wish to seek rather than the average employee who can rely upon an XO or a deputy or someone else to handle that matter.

DR. OSTROFF: Let me just thank you very much for coming.

We're eating into eating time. So I would propose that we move forward with lunch, and I'll turn it over to Rick.

LT. COL. RIDDLE: Yes, probably the best option is probably just the cafeteria of the Uniformed Services University. And I know Ben or other folks who know, three's a McDonald's or some other fast food over at the Naval Medical Center or anywhere in the area. The only thing, if you go off, you've got to get back on, and that's going to make it tough.

And also, for the tour, make sure that you sign up as you leave if you haven't already because we have to turn those over to Security at lunch. So you

probably won't be able to sign up after you get back. And the sheet is out with Lisa outside.

You can walk over to McDonald and over to AFES (phonetic) and still be on base, but the cafeteria over the school is a good option.

MR. CRISS: Well, I look forward to coming back once again for the annual training and having a full 20 minutes to address conflict of interest.

(Laughter.)

MR. CRISS: Thank you.

DR. OSTROFF: Adjourned until 1:30.

(Whereupon, at 12:21 p.m., the meeting was recessed for lunch, to reconvene at 1:30 p.m., the same day.)

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(1:38 p.m.)

DR. OSTROFF: I think we'll go ahead and get started with the afternoon session. I think almost everybody is back from lunch.

And the afternoon discussion will start with the issue of one that the Board has a long and tangled history, and that relates to the unavailability of the adenovirus vaccine, and in contrast to some of the issues of discussion from this morning, there is a specific question that is before the Board, which is essentially to look at non-vaccine interventions that might be used during the interim time period when the vaccine is not available.

And we will begin the presentations with Colonel Diniega.

DR. DINIEGA: Good afternoon. This is a subject, as Dr. Ostroff said, that the Board is very familiar with and the Board has been very helpful to the services in shaping the policies for the use of the vaccine.

Didn't learn from this morning.

As those of us who have been with the Board for several years know, the AFEB has been very instrumental in making recommendations to the services

concerning the use of the adenovirus vaccine, and in fact, the services decided at the service level to use it, and Army, Navy, and the Marines have been using it in their recruit training camps.

And at the very beginning it was a seasonality based use, and then eventually it became a year round use.

The production of adenovirus vaccines Type 4 and Type 7 in oral product ended in 1996, and as the Board members are familiar, the manufacturer had requested financial assistance in order to continue with the production of the vaccine, and the money was never appropriated to assist the manufacturer. So the decision to end came in 1996.

The remaining supplies were extended. Expiration and shelf life was extended based on potency tests. Type 4 vaccine ran out in 1998, Type 7 in 1999, and since 1999, based on the surveillance programs, ten to 12 percent of recruits annually become ill with the adenovirus vaccine.

There have been several outbreaks, and the Board has heard about those adenovirus outbreaks in recruit training camps, and this past year in the summer of 2000, two deaths occurred at the Navy Training Center at Great Lakes.

We got a little bit of an update on the procurement efforts from Captain Yund, but in 2000 the Medical Research and Materiel Command sought new money and was given some $12 million to shore up that effort.

In 2001, the announcement for a request for proposals was put out, and several companies applied, and as you hear earlier, MRMC is ready to award a contract shortly.

Once the award is made, I am told by Mr. Bill Howell, who has been heading the project up at MRMC, that because of some technology transfer coordination, they expect it to take only five to six years for FDA approval and full production.

The question is on the handout that I gave you. Copies of my slides are on the back side of the question.

The Board is being asked by Health Affairs to review known and suggested non-vaccine methods to minimize and/or control transmission of adenovirus, and it applies to other ARDs as we all know, and to also recommend potentially effective non-vaccine methods of transmission and control.

In the past, as we tried to deal with the lack of vaccine, we have looked and the services have

looked and discussed amongst ourselves administrative methods, and they have ranged from head to toe type of arrangements, open windows in the bay.

I remember way back in the late '90s when I was doing basic training at Fort Ord in the fog area, we had fog in our 50-person beds because we weren't allowed to close the windows. And the fog rolled in every morning, cleared up by ten o'clock, and so those sort of things were sort of known to maybe help, but we were never sure.

So the Board is asking to assist the department in reviewing the literature, looking at the scientific data, and making recommendations for non-vaccine methods of control.

Any questions?

DR. OSTROFF: Thank you, Colonel Diniega.

Let me, before we move on to Colonel Gunzenhauser, let me just mention that Dr. Larry Anderson, who is the Branch Chief of the Respiratory and Enterovirus Branch in the Division of Viral and Rickettsial Diseases at CDC, is here for this session.

Larry, he's been at CDC longer than I have. So, Larry, if you want to come up to the table, please feel free to do so. There are several open chairs, to hear the discussion.

Ready?

COL. GUNZENHAUSER: Can you hear me? Okay. It sounds good.

I appreciate the opportunity to talk a little bit about respiratory disease and some of the interventions, at least the experience of the Army with these interventions to try and control ARD, or adenovirus.

Really, first of all, I want to give credit up front to Mr. Terrence Lee, who's sitting in the back. He works up at CHPPM in the Disease Control Branch, and he put this slide set together, did quite a bit of work, and handed it off to me, and I'm doing the presentation for the Army.

I have some background with this. I was the Respiratory Disease Control Program Officer back in '88 to '92, when we had quite a few outbreaks, and have had a longstanding interest in respiratory disease. So I was glad to give this presentation to you all.

Next slide, please. Oh, it's me.

Okay. Really what I want to do is give a little bit of background because I think as the first presenter I'd like to give a little bit of perspective, at least my own personal/professional

perspective on this opportunity and challenges we have; review, sort of give a framework on what some of these interventions are; talk about some experience we've had, what our policy is; and give the results of a survey that Mr. Lee conducted, and you can sort of see where we're at in the U.S. Army.

Okay. Now, the first slide that I put up here, I know this is pretty basic, but often in epidemiology, particularly with communicable disease control, I think it's very good to go back to fundamentals.

One of the things that dawned on me after I had worked with respiratory disease control for a number of years was, first of all, we've been immensely successful. I mean, that's sort of the starting point in the '90s, that the serious disease is influenza, tuberculosis. That was a huge problem in World War I. Meningococcal disease, streptococcal disease, acute rheumatic fever, atypical pneumonia, finally adenovirus, and other things were tremendous problems.

And so the scope of the problem we're looking at today is pretty small, but realizing that we have had a step backward makes this very important because it's heading in the wrong direction.

I throw this up here because what it dawned on me is that for all the modes of disease transmission the two that we're talking about are the top two, and as I've reviewed the literature and been involved with people to try to effect control measures, we're not really clear about which of the first two we're often talking about, whether it's really an airborne agent or a direct person-to-person type of transmission.

So you'll see people doing hand washing, trying to prevent person to person, or they'll be talking about air filtration or cleaning the air, which is really an airborne.

And what it really speaks to is our lack of knowledge on very fundamental aspects about respiratory disease transmission. There's quite a bit of information out there suggesting one way or another, but from my point of view, we're sort of groping in the dark because we don't really know exactly where or how the agent is transmitted.

The other part here -- I realize I probably should have set up a two dimensional matrix -- is that for the other modes of transmission, we by and large have what I consider environmental or personal hygiene modes for preventing them. And so

even though if you think about the vaccines that are in the American inventory, most of them are targeted towards respiratory disease, measles, mumps, rubella, varicella, pneumovax, and you go on and on, influenza, adenovirus. There's only a few of them that are really looking at fecal-oral.

Some of them like typhoid we don't have to use because we've got multiple barriers that protect the health of American citizens.

So if you think -- one way to think of this is that we've got the non-vaccine or the environmental sanitation hygiene approaches, and then we have the agent specific vaccine or other biologic approaches to prevention.

And we've been very successful by using the former measures in the bottom five categories, by and large, whereas with respiratory disease, we have a virtual total reliance on vaccines or biologics in preventing disease.

I know that's not completely true, but that's just sort of my personal perspective, and what I see is that we're in a position now where we're trying to study adenovirus more thoroughly, of trying to understand some of the more fundamental epidemiologic factors that are key in perhaps

developing strategies that work in that formal area.

I know that some of you, many of you probably are familiar with the work of the commissions over the years. The commissions that came up in the '40s, there were really four that worked largely in respiratory disease are. One was the Commission on Acute Respiratory Disease. John Dingle led that one, I believe.

There was a Commission on Airborne Infections, a Commission on Pneumonia, and also a Commission on Meningococcal Meningitis, and all of them did very interesting work in very different areas, and a lot of that work is hidden away. I know it's written in reports, and the summary, the Textbook of Military Medicine, a book that has to do with the history of the commissions, refers to studies and findings and things that I can't find published, at least not in the open literature. I presume it's somewhere, but there is a tremendous history of efforts back in the '40s and '50s and '60s to prevent respiratory disease transmission.

Of course, the Commission of Acute Respiratory Disease was at Fort Bragg. Alexander Langmuir was a member of that team. They really study what eventually we recognize as adenovirus, and that

was one of the main things that they looked at there at least in 1943.

The scope of their work was pretty broad, at least this one particular commission. And really what we're talking about is prevention and control measures.

I really don't have time to go through, you know, the many things that they did. There's a brief summary for those who would like to look at it in the Textbook of Military Medicine that just points out -- it's about six or seven pages -- all of the major findings that came up through that work, many things that didn't work, by and large, some things that had a marginal effect.

They were trying to purify the air. Glycol vapors, some papers seemed to show that it had a 15 to 25 percent protective rate. There's other people that have used ultraviolet filtration in preventing measles transmission in pediatric populations, et cetera.

Oiling of floors and bedding. This had tremendous appeal to the military because it created a very disciplined environment where there was no dust around, and they loved it for that reason, but it seemed to have had a marginal effect on preventing

transmission.

DR. OSTROFF: What did it do to injuries?

(Laughter.)

CAPT. SCHOR: Ethylene glycol is now known to be a testicular toxin.

COL. GUNZENHAUSER: Exactly. A good reason to abandon.

(Laughter.)

COL. GUNZENHAUSER: But oiling was attempted, and particularly with streptococcal disease it did not have any effect on preventing it in certain studies.

Double bunks were looked at. Some of the studies showed that it also had a marginal protective effect, and most of the other ones down here I couldn't find the reference.

I talked to Mr. Lee about the chilling of subjects. There's a reference in there that soldiers that were afflicted with respiratory disease, they would chill them, and I think they were trying to see if that would prevent transmission, but I really don't understand what they were doing in that study.

The point is there were scores and scores of very interesting studies that were done to look at environmental sanitation and hygienic approaches to

controlling respiratory disease in various settings.

Findings were, at best, marginal. We have the legacy of a few things that are sort of left that are advocated nowadays, but by and large when we develop vaccines into the early '70s, the diseases slipped away. So a lot of the knowledge and work that had been done through this commission no longer was a part of the working knowledge of most of the military.

Okay. Now, in the question that was asked to the AFEB, they identified a few areas. Now, I've kind of split these into four. Personal hygiene, of course, is just hygienic measures. The middle two are sort of environmental approaches, and the last one is really a host directed approach similar to vaccines.

Just to review these quickly, hand hygiene, I know you're going to hear quite a bit of discussion about that from the Navy. So I'm not going to get into that, but there have been a whole bunch of different interventions looking at hands as a primary mode of transmitting organisms, and some of them have shown some effectiveness.

Mask, again, has been tried, but we think that from the military's point of view it's not very practical to use these in our training settings.

Administrative controls. A continuing

problem for the military is the space requirement. We have an Army regulation that specifies a minimum of 72 square feet per trainee in their barracks area, and the way our system works, we have a surge of trainees in the summer usually peaking about late July or early August, and oftentimes our five basic training centers, they will approach or extend beyond that requirement so that they're actually below 72 square foot, and they'll call and say, "First of all, we would like to have a waiver, and number two, where's the data to show that this is even a viable requirement?"

And I know we've kind of struggled with that. There's anecdotal reports that have shown some correlation of increased space as associated with reduced disease, but as far as I know, the data is pretty weak at best, although intuitively we think it makes some sense.

Sleeping head to toe is another one of these requirements that if you go to any of the Army basic training centers you'll see it's fully implemented. Double bunking is often common as well.

Cohorting the idea is to try to keep groups together so that there's not transmission between groups, and this can be done more or less

effectively, but studies that I have seen that have attempted to do this have not shown really effectiveness in trying to prevent transmission.

Environmental controls. Dust controls we've talked a little bit about with oiling of floors. Ventilation, there's -- some of you may be familiar, for example, with the paper that Dr. John Brundage published in the '80s on febrile associated acute respiratory disease. It was associated with ventilation, and he found, I think, about a 1.5 increase in the rate of respiratory disease in barracks that used the new, efficient ventilation systems in comparison to older barracks.

That only was observed in the periods before we went to a year round vaccination program. So there seemed to be an interaction between the presence of the agent and the presence of this ventilation system.

And I think that there have been more recent studies. There was an outbreak that I'll point out here in 1998 at Fort Jackson where a team of Army investigators went there, and they found a similar association with a newer type of ventilation system that increased the risk of respiratory disease about twofold for adenovirus among trainees.

The ventilation, dilutional approach, filtration systems, these have all been things that have been discussed and attempted in various settings, but really their association or exactly what the mechanisms are that are involved are not clear.

And, of course, there are these other methods. Some of you may know that at least in Army circles there was a paper that we published back in the early '90s that showed that when we instituted a program of routine benzathine penicillin G prophylaxis at Fort Leonard Wood, we reduced the overall hospitalization rate for respiratory disease by two thirds, which was twice as much as was anticipated based on historical information about what the prevalence of Group A streptococcal infection was.

And so there was some discussion about, well, maybe it augments or has some other effect on bacteria that may be somehow interplay with transmission or whatever. We didn't really know, but we seemed to have this benefit that was unexpected.

There was some further work using the Army's acute respiratory disease surveillance system to verify that. The finding has not been consistently found, but there is an internal sort of thinking that there may be a benefit in preventing acute respiratory

disease in general.

And so people advocate benzathine penicillin G as a possible role for that.

The other antiviral compounds, I'm sure people are familiar in their roles for influenza, and the other things down there, there's some literature out there, but really scant evidence on whether these other things help at all in terms of controlling respiratory disease.

Here's a little bit of information just to give you some perspective on the Army basic training base. We have five facilities that conduct basic training, Benning down in Georgia, Jackson, South Carolina; Fort Leonard Wood is in Missouri; Fort Knox is in Kentucky, and Fort Sill is in Oklahoma.

And what I tried to show on here was the population sizes so that you have some perspective on how many. At the maximum period in the summer, there's about 40,000 trainees. Right now we're a little bit under that at a single point in time, and at the end of summer as it quickly falls off or at late spring, as we continue to ramp down, it will be as low as a total of 25,000 trainees in a given week at the basic training installations.

This is a slide that Mr. lee put together

that shows you our rates. Now, these are a little bit hard to read, but the important -- we have a couple of measures that we follow, and one of them is called the ARD rate, and what this number over here represents is the number of trainees considered a case per hundred in a given week.

So if there was 1,000 trainees here at Fort Benning and it was up at one, that would mean there would have been ten cases. That would have been one per hundred.

And what you can see here -- by the way, this is back in 1990 and '91 -- we had a few outbreaks right here, right here, and also up here of strep associated respiratory disease, and we started bicillin, and we had already had a problem at Fort Leonard Wood.

So for a number of years here four of these installations, Jackson, Benning, Wood, and Sill, were on bicillin for all newly arriving trainees, whereas Jackson, I think they may have gone on it for a brief period of time at some point. I don't remember when, but not recently.

And then this is where we ran into supply problems with adenovirus, and we went to a periodic, certain months when we were giving the vaccine, and

then this is where we ran out.

So what we see here is a definite increase in respiratory disease activity. This is the outbreak at Fort Jackson that was investigated in 1998, and this is up through to this year, and you can see there's been a major increase in the baseline activity.

We consider an epidemic to occur when we have 1.5 per hundred or higher for two consecutive weeks. So you can see back here there was only one incidence where we exceeded that threshold, but recently we've had multiple incursions above that.

I haven't done a formal analysis of this, but my impression is that we have a lot more admissions and hospitalizations during the inter-epidemic, sort of now increased baseline than even during these small outbreaks, and the data that we've received from Naval Health Research Center as part of their febrile respiratory illness surveillance system indicates that over 50 percent of these excess hospitalizations are attributable to adenovirus.

We've got some more recent data. This is the data just from September of last year up through this summer, and again, you can see that for three installations here we've got significantly increased

rates of respiratory disease, here exceeding the epidemic threshold, here not quite, and here at Leonard Wood kind of bumping up over that.

We do monitor strep activity, and I won't go into the specifics of that, but we haven't had problems with streptococcal disease contributing to this problem.

What doesn't show up on this slide is that at the end of July -- oh, no, this right here. This is the largest outbreak of acute respiratory disease that we've had in Army basic trainees in, I think, about 20 years. We had over three and a half -- we had three and a half percent of trainees counted as cases in a single week. That was 252 trainees at Fort Leonard Wood. I think it was the last week of July or the first week of August, and the samples that were collected and analyzed at Naval Health Research Center indicated this was adenovirus that caused that outbreak.

So I think we've shown you pretty much we have a problem.

Now, I should go back just one second because people inevitably are going to ask: what's going on here and here and why aren't they having a problem? You know, it's kind of the rule out. Why

aren't they and the other cases having a problem?

And I've talked with the folks at those installations. I think at least part of it is surveillance. We may be missing some cases, but I've been at places sometimes, and for whatever reason, they don't have cases, and part of the answer may lay there, but we don't know exactly the reasons why their rates are low. But we're working on that to assure that they're counting cases according to the definitions we've set up in our guidelines.

Here's Army policy. When we ran out of adenovirus vaccine, we knew that installations would want some guidance. So in January of 2000 this was put out. This is actually the respiratory disease guidelines that I mentioned earlier this morning, and they include the same thing that was put in here, and that is there's a couple of interventions that might be probably effective. That's as strong as we could advocate for based on the information we have.

So this guidance was put out, and it was up to installations to look at that and decide whether or not they were going to implement those procedures or not.

To ascertain whether or not people were finding this guidance, Mr. Lee did a survey. He

called and E-mailed the five basic training installations this summer and queried them about a number of practices, what they were and weren't doing, and you can see these here, and can interpret some of the information down here.

But basically most people are doing hand washing. Now, note here at Fort Leonard Wood the comments that I got from one of the physicians, the Deputy Commander for Clinical Services, and the fellow that manages the program there is that they had problems with hand washing during this period, and the statement was that the training brigade didn't have money to buy soap and other materials, which I could hardly believe, but that was sort of the story that was circulating.

Whether or not that contributed to this outbreak we really don't know, but they have now instituted hand washing practices at Fort Leonard Wood.

The other thing that we had recommended was sleeping head to toe, and you can see most of them are doing that. Fort Sill, I'm not exactly sure what's going on there, but mostly the other practices are not being observed.

Currently two installations are still

using bicillin: Fort Leonard Wood and Fort Sill. Fort Sill had substantial problems with it a number of years ago, and Benning has used it off and on. I know that as of last year they were using it, but this summer they were not using it.

So that's pretty much the state of what's going on in the Army. This is a summary, hand washings generally emphasized. Space requirements aren't always met. We had the summer surge. This outbreak in July and August is very unusual. It may be associated with that. It was at the peak population period at Fort Leonard Wood.

And this is pretty much where we're headed. One of the challenges in the Army Medical Department is that we don't have a formal research program. We don't have funding to conduct respiratory disease research.

We have an operational mission to control it, but some of the fundamental questions from an epidemiologic perspective that require a teach to go out and deploy we don't have funding for.

I know that General Martinez at the CHIPPM is very, very interested in this, and he's very interested in using existing data to do observational studies.

For example, if we could actually track the square footage of the barracks in which trainees are living and collect a large database and look at the association, perhaps the space requirements with respiratory disease rates, that that might be something that could be done simply.

That summarizes the current situation of respiratory disease and non-vaccine interventions for adenovirus control in the U.S. Army. I'll be glad to take any questions.

DR. OSTROFF: Thanks very much. That's a beautiful presentation.

I looked at this last night, and I was absolutely fascinated by the data from the various installations, and I must confess I don't entirely understand it. I think it's too easy to jump to the conclusion that there's some association with using benzathine penicillin G, but I have a couple of questions before I open it up to the floor.

One of them, and pardon. It's my ignorance. What determines why a recruit goes to one installation versus another installation?

And the second is the thing that strikes me is that the two that seem to be smallest in terms of the training installations don't seem to be having

problems, and the three that are the larger ones seem to be having problems, and I mean, I think what you identified, which is the spacing issue, may -- I mean, there must be some issue related to how they're being bunked at these different installations that must be playing some sort of a role.

COL. GUNZENHAUSER: In answer to your second question first, that intuition may be correct. My experience is that there's definitely some type of threshold or synergistic effect when a trainee population becomes bigger. Somehow a disease process can be amplified not only in terms of transmission, but even virulence.

Anecdotally, my observation is that diseases tend to get worse. We don't understand the dynamics of that very clearly. As I said, we really can't track where the agent is moving or they're hyper shedders, you know, the problem carry, all of those kinds of issues that are prevalent in respiratory disease research.

So it's a good point, and I think you're right. Let me think. Fort Knox, I believe, we can take look at the numbers. I'm pretty sure those are the two installations that have the smallest training numbers. Knox and Sill.

And as for your first question, each of the basic training centers has a specific focus. So like Fort Benning is infantry. Fort Leonard Wood is engineers and chemical and military policy. And so all of them sort of have a focus, and so some trainees will end up there based upon the military occupation that they're going to be specializing in.

But some trainees, I think, can go anywhere, and I don't know exactly how the process occurs. It may be if they're closer to one training center than another that may be where they'll be sent for their initial entry training. But a lot of it has to do with their occupation.

DR. OSTROFF: Dr. Herbold.

DR. HERBOLD: Can you go back to the figure you had that had the chronology of rates by installation?

COL. GUNZENHAUSER: Let's see. That's something I can do here. I think we may be off up there.

Can we look at the handout maybe, Dr. Herbold?

DR. HERBOLD: Yeah. There was a charge where you had the rate, and you talked about you considered it an epidemic if you went over 1.5 per

hundred.

If you could put in the background there the actual census for that training week just to see how that varies, to see if you could just figuratively show that there's some census level that also triggers some type of activity.

COL. GUNZENHAUSER: Yeah, there's always --

DR. HERBOLD: Because your populations per week varied in each post from two to 15,000, and I couldn't see that. You know, when you standardize it by the rate, I can't see what the total census on post is.

COL. GUNZENHAUSER: It would be interesting to look at it that way. Historically our disease outbreaks were usually in the winter, which was when the trainee populations tended to be less, but now that we don't have adenovirus, we have seen these blips in summer.

And it's interesting. For example, two of these outbreaks ceased spontaneously, which is very interesting. If you look at some of the outbreaks years ago, adenovirus can last for a length of time. So it's sort of unusual that they come and go in just a few weeks and we don't really understand the

dynamics of that very well.

DR. HERBOLD: One follow-up question, too. Now, this is basic training. So I'm assuming that all trainees are on station the same length of time.

COL. GUNZENHAUSER: No, that's not correct. At trainees at that installation are counted. There really are three types of training programs. There's a basic combat training, which I believe is still eight weeks in duration.

Then depending upon the military occupational specialty they're going into, they will have additional advanced individual training, which could be anywhere from a few weeks to many weeks, and so depending upon what that is, they could still be in a trainee status for 20-some weeks, whereas some people maybe left after 12 or 15 weeks.

MR. HERBOLD: And then are you always starting a new cohort every week or does that vary?

COL. GUNZENHAUSER: Normally there are new cohort companies starting every week.

MR. HERBOLD: So the introduction of new susceptibles is --

COL. GUNZENHAUSER: Continuous. That's correct.

DR. OSTROFF: Let me turn t Dr. Shanahan

and then Dr. Anderson.

DR. SHANAHAN: Well, I think, you know, certainly the epidemiologic data that exists so far says a lot for crowding, but I think one of the other things to consider is not just the divisions, but when you have this kind of data showing up in Knox and Sill, particularly in AIT, those two operations tend to be small group training, whereas Benning and Jackson and Leonard Wood are primarily large group training.

So not only do you have concentrations of individuals at night, but you also have them during the training period. It doesn't exist to that great of an extent in Knox and Sill, and that certainly would be another thing to look at in terms of crowding.

COL. GUNZENHAUSER: Good idea. thanks.

DR. ANDERSON: Actually, I talked to Frank Top, who worked in this area early on, and he had some observations along that. One of the things is the seasonality. In the Great Lakes training area, they tended to have year round adenovirus disease before they had the vaccine, and in some of the southern states they had more seasonality in the wintertime.

Why that is I don't think anybody

understands, but he mentioned that in one outbreak there was one unit where they kept that unit separate from the other groups, and they tended to have adenovirus outbreaks later in the course of the outbreak; didn't get introduced as quickly.

And I think if you're going to have an outbreak, you've got to have susceptibles. You've got to have introduction of the agent, and then you have to have transmission.

And maintaining virus within the community using small groups, you know, Knox and Fort Sill, where you probably don't have as much interaction and a chance to maintain endemic transmission then of ours may well explain the difference, whereas the larger group you get it in, and you can just maintain endemic circulation within a larger population.

The other thing to remember is that transmission of respiratory agents by and large are contact, droplet and aerosol, but all agents aren't the same, and probably all adenoviruses are not the same in terms of transmission and disease.

And there's some clinical trial data to suggest that Ad-7 and 4 -- and actually the vaccine is a good example -- that route of inoculation of the virus is important in the disease outcomes because the

vaccine are not, in fact, attenuated, at least completely attenuated.

The primary mode of attenuation is route of administration of the virus, and there's some volunteer studies -- they'd never do those volunteer studies now -- but where they tried small particle aerosol and large particle aerosol. So adenovirus 4, and I assume it's probably similar for Ad-7 that you reproduced the AIT with a much lower inoculum of virus and more consistently when you got aerosol versus droplet transmission, and you didn't get it with nose drops or the intestinal route.

COL. GUNZENHAUSER: That's good. Thank you.

DR. OSTROFF: Dr. Landrigan and then Dr. Zimble.

DR. LANDRIGAN: Just a historical recollection, but I recall years ago having read some of the original work of Dr. Gorges (phonetic), after whom the hospital in the Canal Zone was named, and he was looking at TB, not adenovirus, but he found that space between bunks was a critical determinant, and I think he actually had some curves.

And I'm not sure, but perhaps that's where the 72 square foot comes from.

COL. GUNZENHAUSER: Are you familiar with that, Joel, that work by Dr. Gorges?

DR. GAYDOS: Joel Gaydos, DOD, GEIS.

What you may have been looking at was some of the influenza data from World War I because in the United States Army, there is a relationship between the influenza data from World War I and the eventual settlement on the 72 square feet, and that's probably some of the best data around.

And I think some of that might have been accumulated during his tenure.

DR. OSTROFF: Dr. Zimble.

DR. ZIMBLE: Jim Zimble. I just remember about ten, 12 years ago in the Navy review that one of the items that occurred in recruit training centers was mass brushing of teeth, that they would line up in an open trench and it was herd brushing.

(Laughter.)

DR. ZIMBLE: And that let out a terrific degree of --

(Laughter.)

DR. ZIMBLE: -- that moved around. So I know they put up some individual barriers, and they still are doing herd brushing, I believe, but I wonder how much that relates to --

COL. GUNZENHAUSER: I hadn't heard that story before. That's interesting.

DR. OSTROFF: Are there other comments or questions?

GEN. CLAYPOOL: Just one quick question and one comment.

Now, the question is: has there been any change in the serotype prevalence since the vaccine has gone away? And is it still four and seven?

COL. GUNZENHAUSER: It's predominantly four. The figure I recall is 95 percent. I think that may show up in the Navy's --

GEN. CLAYPOOL: And then the comment I have is has there been any -- do you have figures in terms of how many troops have had to have been recycled through the training?

Because if so, time is money in terms of the retraining commands, and that would be something useful to know, I think.

COL. GUNZENHAUSER: I think that maybe Dr. Niebuhr has some information. I think when maybe -- well, I'm not sure if Dave's got it.

Dave, do you have any information on that from when you were at Fort Knox, the recycling?

Yeah, but not from this. I think that

it's not perceived as an issue by the training brigade because by and large it's a low morbidity condition requiring two or three days of care, and they return to duty and the vast majority don't get recycled. So from that perspective they don't see it as an issue because they don't see costs associated with that.

DR. OSTROFF: Dr. Haywood.

DR. HAYWOOD: Are the demographics the same in all of the locations?

COL. GUNZENHAUSER: Our system does not track demographic characteristics. I know that we looked at sex years ago. We do report whether the gender is male or female, and I believe that historically we haven't had the disease rates in women, but I think more recently we've had more involvement of women. But otherwise we don't look at any other demographic characteristics.

DR. CAMPBELL: I'm wondering about the civilian population. If you compared the incidence patterns in the civilian population to this, if it's the same virus that's circulating in the civilian population is affecting these or is it something unique about the military population, such as stress, lack of sleep?

COL. GUNZENHAUSER: That's a good

question. I don't think we've done recent studies to verify that it is or isn't affecting. I'm sure that it creeps over. I know in some other work that I've done where we've looked even in the same military installation at other populations they're at best minimally affected.

Sometimes we look at the cadre themselves, and they can be involved, but I don't know of any knowledge showing that adenovirus is -- it could be introduced by a key situation which we have yet to define from the local population, but I think it's purely the dynamics of the training base that facilitates the spread.

DR. CAMPBELL: Have there been epidemics in civilian populations reported?

COL. GUNZENHAUSER: I think that there was an outbreak of adenovirus reported, geez, it might be five years ago in a college or some type of school situation. Before that I think there were very limited reports.

Of course, other military training in other countries has had problems with adenovirus, but there has not been a lot of reports of adenovirus outbreaks in civilian populations.

DR. OSTROFF: That skilled nursing

facility in Louisiana.

DR. ANDERSON: We do see outbreaks in closed communities.

COL. GUNZENHAUSER: Yes.

DR. ANDERSON: And I think there's probably a suggestion of some respiratory disease in a larger -- from the community in one of the outbreaks I'm actually going to talk a little bit about in Chicago.

But we have very little or really no information other than outbreaks that we hear about and do some follow-up investigations on. But it does happen, but it's not real common.

DR. OSTROFF: Dr. Bradshaw, and then Dr. Diniega.

COL. BRADSHAW: I didn't ask to.

DR. OSTROFF: Oh, I'm sorry.

Ben.

DR. DINIEGA: Several years back, I think this was in the '90s, the mid-'90s. We were approached when I was at the Army Medical Command at Fort Sam Houston for some vaccine for an outbreak. I think that occurred in a nursing home in Louisiana at that time.

But at the recent VRBPAC where we were

discussing selection for flu vaccine strains, there was mention of the need to use the surveillance programs to take a look at other causes of acute respiratory diseases on the civilian side.

My impression at that point was that it's not normally looked for.

DR. OSTROFF: One more question. Two more. Dr. Berg and then Dr. Gaydos.

DR. BERG: Okay. I was hoping Commander Ryan might be here to comment on her study, but if not, maybe Colonel --

DR. OSTROFF: Yeah, well, we'll hear about that next.

DR. BERG: Okay. Well, let me ask Colonel Gunzenhauser. In looking at the respiratory illness and the effect on hand washing, was there any indication of whether the hand washing had a differential effect in terms of the number of cases?

I can hypothesize that hand washing may be somewhat protective when you've just got a few cases, but when you have an outbreak, it just sort of overwhelms the hand washing.

Has anyone looked at that in the articles that your reviewed?

COL. GUNZENHAUSER: No. I mean, I know

there's the study that the Navy did, but the literature I reviewed, no.

DR. GAYDOS: Joel Gaydos, DOD, GEIS.

Dr. Claypool asked the question about the impact of the outbreaks. The impact in the Army, particularly at Fort Jackson has been on the medical care system, and they had to look at contingency plans down there during their heavy periods.

To the best of my knowledge the training command within the Army has not felt much of an impact, but the medical people have.

The Navy have experienced some difficult times, and I think Captain Yund will address that.

The Air Force has had during their peak outbreaks at Lackland, they have experienced considerable loss both in the medical community and in the line. They kept track of their recycles, an it was up significantly.

With regard to the types of adenoviruses, there was an outbreak a few years ago in a Job Corps training center. There's been a lot of seven in closed facilities. The outbreak that Dr. Diniega referred to was a Type 7 outbreak.

I don't know that we've ever seen Type 4 outbreaks in any communities the way we've seen them

in the military.

The association with the size of the operation anecdotally seems to fit. We've had major outbreaks in the past. After Christmas, New Year's break when we brought a large number of people together, some of those have been controlled or at least there was an association with the downward curve of the outbreak when the space requirement was strongly enforced, and the numbers of new recruits were diminished.

We have had one documented outbreak in the Army in an advanced individual training post, which is the training beyond basic training, and that was at Fort Gordon, Georgia, and that was associated with some recruits coming from Fort Jackson. So we've actually had it introduced into an advanced training post.

With regard to, I believe, Dr. Claypool's question we have looked at the prevalence of antibody in incoming recruits, and there's no difference over the last 30 to 40 years. They're still as susceptible now as they were back in the '60s.

We've had molecular studies done on the wild viruses that are circulating, on the viruses that have been used in the vaccines, and there have been

some changes, but nothing that we're excessively concerned about this time, and the Walter Reed Army Institute of Research has done serologic studies looking at the vaccine, and the more recently circulating viruses, and the last vaccine seeds that were used seem to protect quite well against the existing circulating strains.

DR. OSTROFF: Thank you.

I think we'll have to move on in the interest of time, but my only comment would be when I see things like this, it makes me believe there's got to be some very powerful p values buried in there somewhere for why epidemiologic studies are done.

Captain Yund.

CAPT. YUND: Well, for the last couple of weeks I've really been looking forward to this talk, but yesterday afternoon when I realized that Megan wasn't going to make it east and I was going to be giving it, I started to feel --

(Laughter.)

CAPT. YUND: -- I started to feel a little bit different. I realized I wasn't going to learn as much, and that may be true, that you're not going to learn as much either, but I'll give it a good shot.

(Laughter.)

DR. OSTROFF: It'll be quick.

CAPT. YUND: I'm going to skip over some things that were already covered. If you have questions, please feel free to ask the questions, and if I have to say, "I don't know. I'll ask Megan," I'll say that.

Okay. I think many of us have experienced in one way or another that recruits are for one reason or another more susceptible to respiratory infections and it causes a lot of trouble.

There's a spectrum of disease. Surveillance takes a number of forms targeting different syndromes. Well, ARD and FRI are pretty much the same thing. ILI is a little bit different.

A long list of pathogens, respiratory pathogens, of course, headed up by adenovirus. Many of the pathogens that cause disease, and it's difficult or impossible to sort out from the clinical picture. So NHRC has focused very much on laboratory diagnostics, along with the epidemiologic surveillance to sort out what's going on.

This is a map of the sites that are in the DOD, the NHRC respiratory surveillance system, and a little bit of a code about what specific agents are tested for at each one of those.

Here's a slide I think we can skip over. Jeff Gunzenhauser talked about it a good bit in the last talk, and you're all real familiar with all of the background on adenovirus.

This is the Army data from this surveillance project over the last couple of years. Let me just point out that right about here is where the Type 4 vaccine ran out, and right here is where the Type 7 vaccine ran out. And it's not a real long time frame here, but you can see that there are many more spots, peaks above the arbitrary 1.5 threshold.

This is the non-Army sites, and again, it's the same time frame just about. So Type 4 and Type 7 disappeared at about those two points.

This shows the proportional distribution of the testing results from all of the testing, and the red is adenovirus. The average of all of the cultures that were taken over this entire period, about 60 percent were positive for adenovirus.

The vast majority were four and seven, with four leading the pack. I'm not really sure whether there was any 21 or some other cats and dogs of types, but certainly the lion's share was four and seven.

CAPT. BOHNKER: Any idea why the Navy and

Marine Corps have got the higher rates there? I mean, it's just startling. It doesn't make sense, and I don't know why it would be that way.

CAPT. YUND: I don't know why that would be the case either. Somebody could dial up Megan on their cell phone.

(Laughter.)

CAPT. YUND: She might have something bright to say here.

Some interesting data from the surveillance that recruits, unvaccinated recruits are 12 times more likely to develop a positive test for adenovirus when they get sick, and let's see. Did I say that backwards?

Unvaccinated recruits, right, 12 times more likely to test positive for some adenovirus type, and 41 times more likely to develop a positive test for Type 4 or 7.

Most of the slides up to now were kind of background, and now actually we talked a little bit about non-vaccine methods, and hand washing, in particular. Hand washing was the mainstay of or is the mainstay of Operation Stop Cough, which Megan got underway at Great Lakes, and the data from her work showed that there was about a 45 percent reduction in

out-patient illness, respiratory illness, that occurred very soon on the heels of the big push for hand washing, and this big push, it took several forms.

One thing was the education piece. Another piece was getting the system, the recruit training system to tolerate a wet sink as something other than an improperly prepared space for inspections.

But this is what Megan found after the initiation of Operation Stop Cough.

We heard a little bit about ventilation in the past presentation and the difference between tighter buildings and older, looser buildings, and there's some data that shows that ventilation really does have an effect on decreasing respiratory illness rates.

Air disinfection is interesting. Some of these methods were discussed in the last talk. Ultraviolet interestingly, in the past ultraviolet light techniques were such that they shone the ultraviolet light not just on the air and the pathogens, but on the people, too,a nd there are some concerns about that, but today there are UV systems that don't do that, that only expose air and the

pathogens that they contain.

Great lakes has I don't know if it's one barracks or several barracks that have these UV treatment systems where there's a fan that circulates the air past the UV light, and on the average, the data show that there's about a 20 percent reduction in clinic visits. Now this is not necessarily a 20 percent reduction in cases, but 20 percent reduction of clinic visits.

On the down side, these systems are pretty expensive. They take a lot of electricity. It's not all that easy to retrofit a barracks to have these in there, and the benefit is not huge.

Here are a couple of other methods that have not been studied well. I'm not going to say much about them, but surface disinfection and nutritional things I think Jeff Gunzenhauser mentioned also a bit.

Antivirals, there's a company in the U.K. that has approached Great Lakes. They're very interested in developing adenovirus specific antivirals, and they think that they could do that within a couple of years. They may be optimistic overly on that estimate, but it's another possible non-vaccine mechanism that could apply to adenovirus.

On the other hand, it's beginning to look

like we may be looking at the light at the end of the tunnel as far as the non-adenovirus vaccine era if, indeed, we do get the vaccine back in four or five years.

I'm going to skip over this, and she had a couple of slides in here that talked about or one slide about non-adenoviral control.

A couple of projects that are underway or beginning, NHRC is beginning a large study of adenoviral illness, a serologic study of adenovirus illness in trainees, and interestingly a shipboard surveillance project that's going to involve five different ships in the Pacific fleet with the absence of adenovirus vaccine now for a number of years, an extension. You can assume that we're having a larger and larger adenoviral naive population afloat at sea and in our airmen and soldiers also, and so this shipboard respiratory surveillance project may give us some more information about that.

These are Megan's words, but I think I agree with her sentiment here, that non-vaccine methods are worth pursuing, but we shouldn't do anything to impede the progress toward reacquiring the adenovirus vaccines.

And, of course, the laboratory based

surveillance is going to be important over the next couple of years and after so that we can see the impact of whatever control mechanisms, methods we use.

Here's Megan's team.

So now I'm ready to take any questions and tell you I don't know.

(Laughter.)

DR. OSTROFF: Thank you very much, Captain Yund.

I have one question just to start. Now I forgot it.

David, it will come back to me.

CAPT. YUND: That saves me from one of those "I don't know" responses.

DR. ATKINS: David Atkins.

Do you know the types of studies or types of data that were used to look at the effect of hand washing? I'm just wondering if they aren't long-term studies whether you're seeing something of a regression to the mean.

There's an outbreak; they institute a new program. Lo and behold, the rates go down, but it's actually just part of the natural cycle of outbreaks or seasonal effects.

I mean, do they have like multi-year data

or at least year long data?

CAPT. YUND: I'm really not sure of the time line and the duration of hand washing and the duration of non-hand washing eras that were compared, but that's something that's available, and I can get it for you.

DR. ATKINS: And I had one other question. When the question came up about the proportions of adeno and influenza or others in the Marines versus other sites, is the surveillance for these -- how much does the surveillance vary in different sites?

I mean if some places are doing a better job for surveillance for milder illness, could that account for differing distributions of adeno versus other sources?

CAPT. YUND: I'm sure it could. I'm not sure exactly how much. I think Dr. Gaydos is raising a finger indicating that he has some wisdom on this.

DR. GAYDOS: The Department of Defense consolidated all of its recruit laboratory based surveillance with the exception of a couple of installations. Fort Knox is not included, and I believe Fort Sill is not included.

All of the large training bases are -- all of the surveillance programs at the large training

bases are operated by the Naval Health Research Center in San Diego. They have their on-site individuals. they collected denominator data. They collect laboratory data, and the laboratory work is done within their laboratory, and they turn out all of the reports.

So it's probably about as standardized as it could be, with the exclusion of a couple of installations.

DR. ATKINS: But how about the decision to collect a sample and send it in? Is that their protocol for that?

DR. GAYDOS: They use the same definition. They use what is called FRI, febrile respiratory illness.

DR. OSTROFF: I remember my question. You talked about doing shipboard surveillance because of the issue that now that the cohorts are coming through, going onto ships that have not been vaccinated. Was this an issue in the pre-vaccine era?

CAPT. YUND: Not that I'm aware of. I am not aware of any reports of -- I mean, certainly there have been large respiratory outbreaks shipboard in the past. But I'm not aware of documented adenovirus outbreaks in the past.

So I think that one of the things that this study will do is help sort out exactly, you know, what is the relative proportion of adenovirus versus other agents when there are respiratory outbreaks on ships.

DR. OSTROFF: Ben.

DR. DINIEGA: The focus of adenovirus has always been -- and, Joel, you can help me out if I get lost on these things -- has been on basic training and recruits. We know through various deployment surveillance mechanisms that ARDs are one of the highest causes of morbidity during deployments in military operations, and I can't remember any time where we have gone specifically to look at the etiologies of those ARDs. We have never done that.

There was some report several years back that one of the deployment surveillances done during Team Spirit to Korea, they had obtained some serum, and they were going to try to take a look for antibodies to adeno, and I don't know if that was done.

But we have never looked at other than the recruit and the basic training setting at adenovirus etiologies or any other etiologies.

DR. OSTROFF: Larry.

DR. ANDERSON: A couple of things. In looking at the impact of hand washing and other interventions on ARI or ARD or febrile respiratory illness, may or may not give you information about adenovirus. Now, hand washing is probably always good to emphasize because you'll probably impact a variety of things, and rhinovirus probably is going to be right up there and one that you will decrease transmission with good hand washing.

And you may or may not affect -- did they actually look specifically for decrease in adeno or ARI?

CAPT. YUND: Megan mentioned a little bit about that to me on the phone yesterday, and there was a much less pronounced decrease in adenovirus. There was a decrease, but it wasn't 45 percent, and there was very little impact on more severe forms of illness, and very little impact on admissions.

DR. ANDERSON: I think that's actually very interesting in thinking about transmission and route of infection and disease, or it may be. I mean, there may be some hints there.

The other thing is I think you or maybe it was the previous speaker that commented on differences in the impact of adenovirus disease in different

groups, and I think it was maybe the thought that it was more tacked on hospitalizations and severe disease where someone else felt it really didn't impact the training process.

Two or three days of an ARI, they saw the out patient. It really didn't impact the training process. And I think there, again, there's probably a lot of information in terms of different things that are done, the process of training that actually if you can collect the data might actually help you think about what might work and what might not work.

It seems like there could be an awful lot of information there.

CAPT. YUND: I think there's certainly more work to do.

COL. BRADSHAW: This is Colonel Bradshaw.

I just wanted to mention some of the historical data, and some of this was alluded to, but apparently before vaccines were available, it said adenovirus routinely infected about ten percent of the military crew populations, and it was associated with 90 percent of the hospitalizations for pneumonia.

And then after the vaccine was introduced, the total respiratory disease rates dropped by 50 to about 60 percent, and then the adenovirus specific

rates were dropped by 90 to 95 percent for those serotypes.

And then they mentioned the cost effectiveness studies. The Army CE study, and I think Joel was involved in this, estimated about $16 million in cost savings, and some of that includes the lost time and recycling for training, et cetera.

The Navy study said $2.8 million saved, and some of the data that we have from our recent experience in the Air Force crude estimates, not real cost effectiveness studies, but maybe about $3 million that we lost with our outbreaks.

DR. OSTROFF: Other questions?

(No response.)

DR. OSTROFF: Thank you.

Colonel Bradshaw.

COL. BRADSHAW: Well, good afternoon. My name is Jim Neville.

(Laughter.)

COL. BRADSHAW: Actually I guess you guys are kind of having to get second team here because of the problems with travel for our folks, and that actually impresses me, I guess, all the more that we have such a good showing from the Board, and I just want to thank you all for being here, and it shows

your dedication to supporting us in the military, and certainly I just wanted to take this opportunity to say that I appreciate that, especially when some of our folks aren't able to get here. And just to see this many faces from the Board, I think, is very encouraging for us.

But I am filling in for Jim Neville from our Epidemiology Services Branch down at Brooks Air Force Base to discuss a little bit of the kind of unique and strange story of adenovirus in the Air Force.

We'll start a little bit about some of the nuances of the background of the Air Force and basic training in particular with some of the historical notes that are a little bit peculiar to us. The current status of febrile respiratory illness surveillance at Lackland Air Force base, which is our sole and only recruit training center in the Air force, and then a little bit of what we know and what some of our background is in terms of the non-vaccine interventions.

The Air Force basic training in San Antonio, as I mentioned before, is our only Air Force BMT site. We don't have like the Army and the Navy several different sites. We do it all in one

location.

Historically, however, we had done it at Lowery Air Force Base in Colorado and some other places, and I'll get to that in a moment when we kind of discuss history some more.

We have anywhere from 3,500 to 6,000 basic trainees. We have around 1,000 arriving weekly or so, and that's 50 weeks out of the year. These numbers may increase during the summer as, you know, kids get out of high school and they come into the military. So we tend to have higher numbers at about that time in the summer months.

We have six basic training squadrons. They have ten to 12 flights per squadron, and then that's about 55 trainees per flight.

We have a little bit shorter training period than the other services. It's a six weeks basic training period. In the past there was some postulations or hypotheses that maybe the shorter training period in the Air Force had something to do with the fact that historically we seem to have less adenovirus than the other services, although it's not clear that that's true because you can get adeno, of course, within two weeks of getting into crowded conditions. But that had been a consideration in the

past as to whether the shorter period had anything to do with the epidemiology.

In terms of background, the Air Force actually started using adenovirus vaccine in 1973, and we used it for quite a period of time, and this was during the time period where basic training or at least a portion of was at Lowery Air Force Base in Colorado, and Dr. Micheljohn and Joel and some others that have a longer history in epidemiology than I do might have to help me with that pronunciation, but he studied and looked at both influenza and adenovirus rates in the Air Force over the period of time that we're using the vaccine, and the rates dropped pretty much to about zero or at least very low for a considerable period of time.

And he published a paper in 1983 on this, and in 1987 the Air Force stopped using adenovirus vaccine, and from then on until October of 1999, we had maybe little spotty occurrences, but really no what you would term an outbreak or significant epidemics of adenovirus at Lackland Air Force Base and in our training bases.

However, in October '99, and you've already seen what the time line is on the loss of vaccine, suddenly we have a new large and sustained

febrile respiratory illness outbreak, which was attributed to adenovirus.

Now, it's interesting. We were looking. It wasn't that we weren't looking for adeno. With Project Gargle we were doing occasional surveillance, getting cultures, and we would again get spotty occurrence of adeno, but really nothing that was attributable.

So why did the outbreak start when it did? Well, about this same time we started having what they call Warrior Week, which is one kind of intensive week of training, kind of out in the field environment. That was sort of a temporal association, but we don't really know why.

The other question that comes up, of course, is were we benefitting in some way from some sort of herd immunity. All the other services, Navy, Marine Corps, the Army, were using adenovirus vaccine. In a minute you'll get the background on the Coast Guard, what they were doing, but we don't know if that's the case, but certainly it seems to resurface now that nobody is using adenovirus vaccine much anymore because we don't have it.

On your left-hand side it shows what happened initially. We had this low rate kind of

smoldering along of, you know, adenovirus here and there, and suddenly in October of 1999 as the winter season started, we had this big, significant increase in adenovirus, so much so, and it was on a recurrent basis, that we had to open a new in-patient ward at Wilford Hall Medical Center, and we're having anywhere from 13 to 16 admissions a day, I believe, in some cases of recruits for adenovirus problems.

We also happened to notice that in the following year, in 2000, that we had a continued kind of increase, and it was a little bit more sustained in the summer months. I'll show you a better slide of that here in a minute, but we also noticed a kind of a three to five-week cycle of adenovirus, and of what significance that is it's hard to say, but there may be something to look at there.

As part of the outbreak investigation of these issues and problems, Dr. Neville and some others did some evaluations to include a questionnaire, and they noted some hygiene deficiencies.

You heard earlier when Jeff Yund was speaking about the Great Lakes experience that hand washing and wet sinks are an issue for TIs or training instructors. They don't tend to like them.

And so there was a tradition passed on,

and it was occurring even at the time the outbreak investigation was done where the recruits would off the water supply to all the sinks except one because it was much easier for them then to keep that one sink dry, which was the requirement by the training instructors.

So these issues of being able to wash your hands and having to queue up in line just to wash your hands were an issue.

Of course, they noted also in the survey that respiratory illnesses were common. They did some studies actually where they looked at air quality in the classrooms and in the sleeping facilities, and it seemed to be that in the classrooms in particular there were problems. They had four out of four of the classrooms where carbon dioxide levels were over 1,000 parts per million over recommended levels, and if you see the recruits once they're in the classrooms, they're really in these small desks, shoulder to shoulder, very narrow space in between, crammed wall to wall, and they don't have good ventilation there.

They have one door. In the kind of spring and fall, they can afford in Texas to open those doors and get more air in there, but as you might expect, in the heat of summer and the cold of winter they're not

very likely to open those doors. So they have a problem with air quality there.

DR. OSTROFF: How many of them were awake?

(Laughter.)

COL. BRADSHAW: Actually they're pretty upright, at least when I saw them, but it wasn't after lunch.

They also noticed that many people who said they were ill, maybe as many as 60 percent, did not actually seek medical care. So even though they described illness that would fit, a lot of those people did not seek care.

Even though we mentioned some of the issues on cost and so on, there was kind of a variable impact on trainee throughput. Most of the trainees were able to finish their training and not have to be recycled, although there were some that did. So there was increase in recycling, but all of them were able to finish training, I guess is what I'm trying to say.

This is just some more detail from the survey results. I just talked some things on compliance with hand washing, for instance, and those that had cold and flu symptoms, those that report and those that don't report, the ability to identify behaviors that might be conducive to limiting spread

of disease, instances of personal hygiene, et cetera, just simply questions like who used tissues, who doesn't, who can, who won't be able to.

And then some things from the military training instructors, as well about when they observe trainees washing hands and what kind of things might they convey to them in terms of proper hygiene.

Now, this is kind of what's going on currently at Lackland. It is, as has been mentioned before, one of the sites in the Naval Health Research Center respiratory illness surveillance network. So we do participate in that actively.

We do have an assigned research assistant, which we've found has been very important to making sure these things happen because you really need somebody on top of it, and making sure it happens. They kind of remind the clinic personnel to sample for people that have febrile respiratory illness, and then we forward these.

There is kind of a minimum number of cultures that need to be submitted, two per thousand per week at least or every fifth case in some cases.

The ambulatory data collection is kind of dependent on how well the staff is motivated, but we do try and collect that information, too.

This, again, shows how we've stayed above the epidemic threshold even in recent weeks. So it's still an ongoing problem there. The red line is actually the current year, and the blue line is the previous year.

And I think the main thing to notice here is that we're still peaking with outbreaks, but we also notice in the summer months at each end of this graph that the rates have been staying kind of elevated. So it seems to have kind of found a home at Lackland.

It just shows in this slide some of the survey results, but we average around 70 percent adeno right now in the current situation.

Some of the interventions that are non-vaccine type, we've gone to our colleagues at Great Lakes and in the Army and found out what they were doing and tried to emphasize some of those things in our setting.

We do have an emphasis on hand washing. We've given the instructors training manuals, and they are to brief all of the new trainees, including the medics coming in and making special presentations; have posters and flyers posted around now.

There have been some attempts to de-crowd.

I may need to borrow that slide from Jeff Yund where they had the folks in the kind of puzzle posture there sitting behind each other, but we have issues like that where before they were supposed to save space and stand close to each other in line and breathe down their neck, now trying to get more space between them.

We do use the head to foot sleeping orientation. We've gotten the command and the TIs to allow us to have wet sinks, and that's now kind of mandated at the recruit training level, and we're trying to make it allowable to use facial tissues and other things like that. I'm not sure how much difference that makes, but whatever it might help.

This is just some more information on what has been briefed. This is an actual slide actually out of what the MTIs are using and training for them, reiterating what I mentioned before.

What we want to do in the future through FIERA (phonetic) and Lackland is periodically surveying and to see if folks are actually complying with the hand washing.

Roger Gibson who was here earlier today is now at Health Affairs, but as part of his doctoral thesis did a study of ethyl alcohol hand wipes along with PCMX based hand wipe and observed hand washington

and looked at several types of respiratory illness, including strep throat and some other things and was able to see some differences there.

I have a short slide where you can kind of look at the brief study of those results and then, of course, maybe reevaluate the issues about indoor air quality, particularly in the classroom spaces.

This is a little bit hard to read, but this is some of the results in using antimicrobial hand wipes versus placebo hand wipes, and you'll notice particularly for acute URIs, sore throat and strep throat that the p values were significant for that versus placebo hand wipes.

You may want to get in touch with Roger Gibson to maybe look at this data further if you'd like.

DR. OSTROFF: What are those values?

COL. BRADSHAW: Do you want to go back? I'm sorry?

DR. OSTROFF: What are the values?

COL. BRADSHAW: The antimicrobial -- they don't have it labeled real well here. They had an n of 50, I think, or a relatively small n. So it was in the range of 50, and so I think this may be part of the counts and who came in.

I have the abstract if you'd like to look at that, and then Jim Neville can make available or Roger Gibson can make available the full study.

DR. OSTROFF: And these are percentages?

COL. BRADSHAW: Yeah, I believe so. Unfortunately they didn't label this well, and not being my slide, it's a little hard for me to talk to it. So I apologize for that.

LT. COL. RIDDLE: I've got Jim's full study, and I've also got his thesis, too, for background material.

COL. BRADSHAW: Okay. Yes, sir?

DR. ANDERSON: I think the story at Lackland Air Force Base is very interesting, and the comment that you said that adenovirus has found a home at Lackland Air Force Base, it sounds like that's actually the case, and I think actually what that points to is, I think, mixing of recruits now that did not happen earlier, i.e., recruits that have been there for four, five, six weeks, and those that are coming in such that you get it going in a group, and then you transmit to the new group that you may not have had earlier.

And one of the questions is: do they develop a buddy system? What's Warrior Week? What

specifically happens there?

And it's the detail of those inner actions that may well give you the clue and the intervention to get adenovirus from taking residence in Lackland Air Force Base.

COL. BRADSHAW: Yeah, there is more data probably than I've presented because obviously it's a little hard to cram it all in, but they did do some serious surveys or cultures as people came into training, and they found about a 16 percent prevalence of adeno, and by the end of training, I think, with either sero surveys or cultures -- I forget which -- about 60 percent had evidence of adenovirus infection once they left training.

So obviously there's some spread.

DR. ANDERSON: Well, yeah.

COL. BRADSHAW: You would figure that.

DR. ANDERSON: But, I mean, the question is what's different about how the recruits interact.

COL. BRADSHAW: Right.

DR. ANDERSON: And what you're saying, i think, that the data is that recruits that have been there are transmitting to the new susceptible recruits, and you didn't have that before.

COL. BRADSHAW: And it's getting carried

on.

DR. ANDERSON: And so there's something different about the way they're handling recruits, I think.

DR. OSTROFF: Can I ask what happens when one squadron leaves and the next one comes in in terms of cleaning the barracks? I mean, could they be leaving fomites from the last group over into the next one?

COL. BRADSHAW: It may be true. I can't speak by personal knowledge of that, but it's certainly one thing we could look into.

DR. BERG: Bill Berg.

One of the problems with stressing hand washing in the hospital is lots of hand washing leads to dry, cracked skin, and nurses and doctors don't like it. Did you see any of that, particularly when you started to push the hand washing to a minimum of five to six times daily?

COL. BRADSHAW: I don't know if we've had much problem with that. I do know that we had recently a case of invasive Group A strep, but whether that originated, you know, in the hands or elsewhere, I'd have to go back and find the clinical case where that occurred.

But they actually went to, I think -- they may have gone to doing the benzathine penicillin because of that.

DR. BERG: The second question: what does the -- about how much does the PCMX based hand wipe cost?

COL. BRADSHAW: I don't have the data on that, but Roger Gibson could probably get it to you.

CDR. LUDWIG: Dr. Gaydos.

COL. BRADSHAW: Joel?

DR. GAYDOS: Joel Gaydos.

I think there was something else that happened at Lackland, too, Dana, and my understanding was that it was temporally related to the outbreak, and that was the Joint Service Language School, where they brought in people from other services. I know they brought them in from the Army at Lackland to the language school, and I know that some of the people think that the introduction of soldiers to Lackland for the language school coming out of Army training centers preceded the large outbreak of adenovirus, the first large outbreak.

COL. BRADSHAW: Yeah, actually there's several joint schools of which the Defense Language Institute is one. They have some others that train

military working dogs. They even bring people in from South America up to do Spanish Language training.

So Lackland is a mixing bowl of certain sorts from other services, the security police schools, and those are in some of the background notes that Jim had, and I meant to mention that earlier. So I appreciate you bringing that up, Joel, because that is one potential for population mixing. He just didn't have it on the bullets that we had here.

DR. OSTROFF: Captain Schor?

CAPT. SCHOR: Just to mention down at Paris Island the Marine Corps doesn't do hand wipes, but they've been doing non-water based hand cleansing. It was driven by an Inspector General requirement because the Marines complained that they didn't have time to actually march the Marine recruits past the CINCs. The training schedule was that tight.

So they figured out how to make bulk quantities of gel Marine proof in large catsup containers, pump containers, and they're placed right outside the chow halls, and I guess the Marines are taken to that well enough that they're even putting it on the crucible sites where they go out and around as their final graduation exercise.

But that's been in place for two and a

half years at least, driven by not really outbreak issues, other issues, general hygiene issues I guess you would say, but there are some long-term data there at Paris Island.

And I raise the issue that if you have recycling occurring, I think that may be a very interesting thing to look at, to see where recycled recruits -- how that relates to patterns of ARD, whether that increases the mixing or if you have cohorts that are going fairly cleanly through the training without a lot of recycling, how that may impact things.

Certainly in the Marine Corps with about an 11 week training there's probably three distinct phases. The first one is the initial conditioning and basic training part of it, and then weapons training, and that occurs in different areas. They kind of go to different portions of the base.

On the West Coast, they go to Camp Pendleton, a completely different setting, and then also they finish up with their crucible 72-hour experience of group formation and challenge and things like that.

So some of those mixing and non-mixing of cohorts and different place issues, I think, may be

useful.

DR. OSTROFF: Let me ask one other question, and then we have to move on. What was it that made the Air Force stop in 1987?

COL. BRADSHAW: I believe, as near as I can reconstruct, this article actually was in 1983 where it seemed like after we had instituted vaccination for both adeno and, of course, influenza, that there was all of these low rates, and I think at some point they decided to stop, and it just never recurred.

But it occurred sort of under recommendation from Dr. Micheljohn, I believe, as far as I know. That's what I've been able to reconstruct at least, and Jim Neville --

DR. OSTROFF: I trained in Colorado, and I knew Dr. Micheljohn very well. It's kind of surprising to me --

COL. BRADSHAW: Yes.

DR. OSTROFF: -- that he would have suggested that.

COL. BRADSHAW: I mean, we can try and dig more, but as far as I know, Joel, do you have any information on it?

DR. GAYDOS: Yeah, the Air Force for the

last quarter century at least has had an exceptional laboratory based virology surveillance program down there, and back in the '70s everything was happening on that installation at Lackland, and they still have -- that lineage is still there. In fact, we do all of the DOD -- almost all of the DOD influenza work at Lackland.

And my understanding was that they felt that they could stop the vaccine. They had such a good surveillance program, and what they said was that we don't want the vaccine to go away, but we think we're at a point where we could stop it and conduct our surveillance program and reinstitute it.

DR. OSTROFF: Thank you.

Commander Ludwig.

CDR. LUDWIG: Okay. I'll go ahead and start while I'm waiting for my slides, which I hope are coming.

Adenovirus is a topic that's kind of near and dear to my heart, as well. I followed actually -- I was the second Army respiratory disease surveillance officer after Colonel Gunzenhauser, and it happened that I was there when the Army first became aware of the fact that the vaccines -- there was going to be a problem with the supply.

And, in fact, we had had an outbreak during a lapse of vaccine that was not really related to the same supply problem. It was kind of in a larger sense, but in any case, we had an outbreak at Fort Jackson, and I believe that was, if I remember correctly, it was the summer of '95. I think that's right.

Okay. In Christmas, at Christmas season of 1995, Dr. Gaydos, then Colonel Gaydos, and Dr. Brundage, then Colonel Brundage, myself and Coleen Weese, for those of you who remember Coleen, met, in fact, came in from some of our Christmas leaves to try to develop a response to this issue, an early response to this issue for the Army.

Subsequently, of course, I am now in the Coast Guard, and so I started a surveillance program in the Coast Guard at our one training center, which is at Cape May, New Jersey.

In 1966, by way of a little bit of history, Dr. LaForce, who was then an EIS officer, investigated what turned out to be a culture confirmed adenovirus outbreak at Cape May. These data were never published, but fortunately I found out about it from him at one of these meetings, and I'm very pleased to have gotten the outbreak investigation

report from that.

Despite that outbreak and a chronic problem with respiratory illness, there doesn't seem to have ever been adenovirus vaccine use in the Coast Guard. I could find no record, and there's a nurse who is still there, who's been there since the late '60s, who never remembers an oral vaccine being given. So that was how I judged that she probably would remember adenovirus vaccine.

In July of '99, we began ARD surveillance, and because we're part of the NHRC network, we're calling it febrile respiratory illness surveillance.

Our case definition at Cape May is slightly difference from what was described for the Army, and I think this may be an issue to discuss at some point.

We are taking a temperature of 100.5 or greater with sore throat only, not any other respiratory symptom, and I think maybe either we need to sort that out so that we can come up with some kind of standardization for surveillance purposes.

In any case, in November of '99, we did begin specimen collection and sending them off to NHRC, and these specimens then confirmed the continuing problem of adenovirus as a major cause of

acute respiratory disease.

In the time that we've been collecting specimens at Cape May these roughly two years, 78 percent of our specimens have been adenovirus positive, and most of the rest of them, virtually all of the rest of them have been unknowns.

We have exceeded the epidemic threshold on several weeks, and the first two weeks that this occurred, we unfortunately were not collecting specimens yet, and so we can only say that they were probably adenovirus because we do have some specimens from about two weeks later that showed some adenovirus activity. The others were all confirmed adenovirus.

Here's the other chart that I promised you from my earlier presentation. Again, the blue is the febrile respiratory illness rate, and this is only for the year 2000. I have all of the data, but I just wanted to show one year's worth.

The green, again, is the number of specimens that tested positive for adenovirus, and you can see some similarities, although not exactly parallel to one another.

I will say that this was during our population surge at Cape May. Our surge generally occurs late in the summer and this year is occurring

right now. So this last year we did have an outbreak during the surge. This year so far, again knock on wood, we have not.

I also want to point out here that our population of recruits ranges from 600 or so to 1,000 at Cape May, and so we may be, I believe, the smallest of all the recruit training centers, and yet we have a tremendous problem, what I consider tremendous in the sense that most of our acute respiratory illness is caused by adenovirus.

So I wonder how that fits in with the hypothesis being discussed earlier concerning size of the training center.

We do have some problems, some surveillance challenges -- sorry. Not problems; challenges. The first category, of course, is specimen collection, and the providers need to be reminded, especially in the Coast Guard where there is not this extensive network of preventive medicine officers and people working on these problems.

They tend to want something that's going to be clinically helpful. If it's not clinically helpful, they tend to forget it.

Well, fortunately we have some very supportive personnel both heading the medical system

and heading the training center so that this has become a priority, and we do have some good cooperation.

There was a period last year at some point where we had no specimens for several weeks, and what had happened then and it turned out that we did exceed the outbreak threshold.

But what came of that was increased attention to the whole problem and to the system itself.

We have had some problems with specimen processing. Our people, for whatever reason, many of our specimens, a number of our specimens have been lacking identifying information. That makes it difficult to use them for anything except for gross proportion of specimens being due to adenovirus.

They are only shipping them about once a month or less, and that probably could be done more often. The biggest thing has been getting dry ice for some reason, and I think they now have that problem solved, but for quite a while that was a real problem.

Now, what they've reported having done at Cape May, I've made a number of recommendations for non-vaccine control measures following along all the other services. They report having instituted common

sense preventive measures, including hand washing, enforcing the head to toe sleeping arrangements, and, quote, airing out the squad bays.

At this time, the squad bays are not air conditioned, and although they're newer buildings, they, I believe, are able to open the windows to some degree. So they were concentrating on that.

In terms of head to toe sleeping, they had not been enforcing that so much. So they did concentrate on that. I'm not sure exactly what they mean when they say hand washing. It certainly isn't anything formalized, but hopefully there was the wet sink permission, and so on.

The other thing, of course, is making sure they get the vaccinations for other causes of febrile respiratory illness, and we all know that influenza has been a problem.

Preventive challenges. The troop living space requirements for the Coast Guard basic training site are the same as for the Army, 72 square feet per person, and I can tell you I visited there, and I assure you that they're nowhere near having that much space per recruit, and I'm not sure what can be done about that.

It is in our regulations, and it's not

being adhered to. We have three-bed bunks, and they're all, you know, four feet from one another. And, in fact, they try to crowd as many people into as few bays as possible because then they can close off the other bays.

And I have suggested that they plan for making some of these unused bays available during epidemics, and I don't believe that's going to be an option, at least not so far.

Hand washing policy we need to address further.

We have limited holding area. We don't have a hospital there. In fact, Coast Guard has no hospitals, but they do have a holding area that can hold up to 25 people. That is currently in the plans to reduce the holding area capability. And so during a surge we may have some problems.

The influenza vaccine delays and the surveillance challenges that I already mentioned.

That's all I have to present. I wish it were more helpful, but it's what we have.

Are there any questions?

COL. BRADSHAW: Yes, thank you very much.

One question I have, I think it was asked earlier by Dr. Haywood. Is there any epidemiologic

information to look at? I mean incidence in males versus females or anything like that amongst the recruits.

CDR. LUDWIG: I believe that NHRC collects those data as part of the febrile respiratory illness project, and perhaps Dr. Gaydos can speak to that. I believe they collect those data. I don't have them.

DR. OSTROFF: Yeah, I'm just wondering if the female barracks are equally crowded as the male barracks and things like that.

CDR. LUDWIG: Oh, they are, but the nice thing about the female barracks, with as small a population as we have at any one time, even though the female barracks are also small and crowded, there are may be nine or ten in any barracks at one time, females.

However, interestingly enough, the female barracks are -- to get to the female barracks, you need to go through the male barracks, and it's just a partitioned off area. Actually it's walled off, but it's just beyond the male barracks. So they have to go through that area anyway.

It's really awkward --

(Laughter.)

CDR. LUDWIG: -- because any time a female

needs to go to her bay, she has to go through this very regimented procedure to get all of the males, make sure that they're all dressed or aware that she's coming through.

DR. OSTROFF: How's compliance?

CDR. LUDWIG: With that? Compliance with anything at basic training is very good.

DR. OSTROFF: Other questions?

(No response.)

DR. OSTROFF: If not, thank you.

Dr. Anderson, and then we'll take a break.

DR. ANDERSON: Well, I'd like to thank the organizers for asking me to participate in this very interesting discussion on adenovirus prevention in light of the unavailability of the adenovirus vaccine.

And one of the things we're involved in CDC frequently is outbreak investigations, and in the course of outbreak investigations, it's an opportunity to come in and prevent disease, although I think more often than not we really ride the down slope of the EPI curve.

But the other thing it does do is allow us to learn from experiments of nature, and what I'd like to do is look at some of our experiences of adenovirus outbreak investigations from two perspectives. One is

routes of transmission and also routes of infection and impact on the outcome of that infection, i.e., disease, and then procedures to prevent and control outbreaks.

And in the probably more '70s and '80s, we investigated a lot of outbreaks of epidemic kerato conjunctivitis, and most often associated with ophthalmology clinics, and we learned quite a bit from this, and this is just one outbreak that we investigated.

It was a large outbreak in a series of ophthalmology clinics and hospital in Chicago with about 150 patients a day in 28 clinics. And from July 1985 to January 1986, there were 401 cases of EKC identified in this outbreak. One hundred and ten were nosocomial, and then there was an ongoing community outbreak which actually provided a way to look at infection control with continued introduction of the virus into the hospital setting.

And what they did early on in the course of the outbreak, they educated the medical staff about hand washing, isolate cases, make sure you disinfect equipment, limited procedures, and exclude ill staff.

And the outbreak continued, and then in September they actually went by to make sure the

people did it. They instituted additional measures, triage, and cohorting patients. Basically they had a red eye clinic. When someone came in with red eyes, they went to a different place to make sure they didn't mix with patients that didn't have red eyes.

Unit dose medication to make sure you weren't transmitting with medication, and then surveillance and let the staff know how they were doing.

Well, this slide kind of illustrates what happens, and the yellow line is the community outbreak, non-nosocomial cases that came into the ophthalmology clinic.

The blue bars are the nosocomial cases, and the little red V is August 8th, when they introduced the first infection control measure, education, telling people what they're to do, and the second bar is when they enforced it and introduced cohorting and other measures.

And what this tells is it's tough to stop adenovirus outbreaks. It really is, and we'll see this in the other cases as well.

The other thing about adenovirus is it's a non-envelope virus, and therefore, it's a kind of a crystalline structure which is difficult to

inactivate. It's an activator with soap and detergent, although soap and water is effective because it dilutes and cleans, but not in terms of killing the virus.

And also because it's a stable crystalline like structure, it can remain viable in the environment for prolonged periods of times in solutions such that its fomite transmission is a real and likely mod of transmission.

The other thing in this outbreak is tonometry was associated with EKC, and that highlights the route of infection import in the disease outcome, that you inoculate directly ont to the eye. There may also have been some trauma that made the eye more susceptible. It also was a mode of transmission and a fomite in itself, as well.

Two other outbreaks, and this gets a little more home to what's of interest here. Ad-7, a couple of outbreaks of Adenovirus 7, acute respiratory illness with a high incidence of severe disease, hospitalization and death, and these are in closed communities of children with some kind of predisposition to severe illness.

And then the first one is in Chicago with 91 nonambulatory residents with severe neurologic

disease, a chronic care facility. Between September and November, 31 clinical cases, 11 ad. positive, eight deaths.

First, in terms of infection control, I'm going to talk about transmission in a secondary facility, a hospital that admitted cases from this care facility. And they have 36 health care workers ill, five adeno positive, and one case of transmission to an in patient.

And they instituted droplet contact isolation, intensive hand washing, restricting ill employees from working.

And the question is: did it work? Well, if you look at the EPI curve -- and they instituted the infection control procedures about October 28th, and if you assume a five to ten-day incubation period, it really took a while or had relatively minimal impact early on in the course of the hospital outbreak. Eventually it probably did, or you eliminated your susceptibles.

Now, one of the things they did is they administered a questionnaire to the health care workers to see how well they complied with the instructions that they were given, and this illustrates one of the big problems in infection

control and health care facilities, and the bottom line is compliance.

It's really hard to get health care workers to do what they need to do, and in this survey 28 percent of the people said they did the strict droplet precautions, et cetera. Thirteen percent said they used face masks when they were supposed to, and 83 percent said they actually took care of patients while they were ill, although they were instructed not to do so.

So compliance is really a problem in any kind of infection control procedure. I don't know how it is in the military, but I suspect you may have a compliance problem as well.

This is an outbreak again in a pediatric chronic care facility, and 50 ill patients, mental retardation or development disabilities, 42 clinical cases, 30 ad positive. Interestingly, eight of the non-ill patients were ad positive, and they may have infected every susceptible patient in the course of this outbreak. I mean, they did a lot of isolation detection. So they really had a pretty good handle of the majority of people that were infected.

Again, a lot of serious disease. Twenty-six of the 50 were hospitalized. Seven of the 50

died. So severe outbreak.

Now, what do they do in terms of infection control? They really had a lot of things that they tried to do. They tried to educate people about cohorting, hand washing; tried to cohort staff and ill patients to make sure that there wasn't a mixing phenomenon. I don't know how effective they were. And no new admissions and group activities discontinued.

If you look at the outbreak and when they instituted control measures and you think of a five to ten-day incubation period, my suspicion is that their infection control had almost no impact on the course of the outbreak. It may have delayed it a little bit. I mean, I really don't know, but it certainly didn't prevent nearly all of the patients or maybe all of the susceptible patients become infected.

Again, it's touch to control adenovirus outbreaks at least in health care settings.

And this, just to switch course. Now I'm going to talk about route of transmission and think about how that may affect disease, not in terms of infection, but the outcome of the infection, and this is just what I mentioned earlier,a nd you folks have probably talked about this previously, that the

adenovirus vaccine is based on attenuation by route of infection, not by attenuating the virus.

And for aerosol, not all of the information is actually helpful in thinking about it is on this slide. Aerosol, you get a high rate of everybody that was inoculated, was infected, and they had around ten infectious units.

The droplet, they had 1,000 infectious units. They actually inoculated six people. All six were infected. Three had illness. So higher titer of virus, although the numbers are small and you have to be careful about saying that's reality. There is a suggestion that for the droplet transmission you need more virus to get infection and certainly to get disease than you do the low respiratory tract.

Well, do we have any data in the course of these outbreaks? And we're probably a little bit short on time, and I think I'll just skip over how we did it and talk more about the results.

And looking at it two ways: one, in terms of association between susceptibility, and really the thing I'm interested in is tracheostomy, and the reason is the historical data about the route of administration being important in disease outcome and the fact that in most of these outbreaks there have

been chronic care facilities where a high percentage of the children or at least those who were more severely ill had tracheostomies in place and kind of thinking of direct inoculation into the respiratory tract, into the lungs.

We don't have data to confirm that that is actually what's happening, but that's the hypothesis.

What you see here is that in the ill patients you've got a higher rate of tracheostomy, but that's a fairly small percentage of all the infected cases.

When you look at it a little bit differently, and here you're looking at the course of disease. If you weren't ill, there's a fairly low rate of tracheostomy, and that could be if you got a trach, you're more likely to have manipulation, inoculation of the virus.

If you did get ill, tracheostomy was much more common in those that died. Now, that could be route of inoculation meaning more severely ill. It may mean that children with tracheostomy had a more compromised respiratory tract and, therefore, more likely to die with illness.

It could be that because of the manipulation it was easier to put more virus down

there. So I don't really know which of these factors is coming into play here, but it's certainly consistent with the hypothesis that route of infection may be important in disease outcome.

In the Illinois outbreak we actually looked again at that, and here a much higher percentage of the children had tracheostomies, and here we're looking at illness in those who survived and those that died. All of those that died had tracheostomy. A lower rate had tracheostomy in terms of cases survived and then the non-cases.

Now, when you turn that around and look at just those that were adenovirus positive, which is probably a better way to look at this, what you see is five out of the five cases that died had tracheostomy. Of the clinical cases, 13 out or 14 had tracheostomy, and then eight out of the 11 or the hospital cases, 13 out or 14 had tracheostomy. Of the non-hospitalized cases, eight out of 11, and then of the non-cases that were infected, one out of three had tracheostomy. Suggestive, but it's really just suggestive.

So we come around and what are the conclusions to these? First of all, adenovirus is difficult. Outbreaks of adenovirus are difficult to control the motor transmission because of compliance

problems, the fact that the virus is very stable and can sit around in the environment and transmit by fomites quite easily and quite effectively.

And whether or not you can do environmental changes, air handling, crowding, and those kind of things, I don't know. I mean, you may have information that you've already -- that's available in the different institutions that may help you.

I think the one thing that may make a difference is the concept of cohorting or at least preventing mixing between new and older reports, particularly in the context of an adenovirus outbreak, and that might be the simplest thing that is historically likely as a good chance of being effective.

And I think the idea of route of infection being important not in terms of infection, but in disease outcome, and the difference that you suggested or one of the speakers suggested in severity of disease in some groups versus others potentially may be that there's a different primary mode of transmission.

Adenovirus can certainly be transmitted by aerosol. It can certainly be transmitted by fomites

and also, I'm sure, by droplets and context. So all modes of transmission come into play, and what may possibly be important, which is the primary mode of transmission in terms of a disease outcome? We don't really know, but at least those are some of the things that at least I've thought about thinking about this particular problem and the question you're dealing with today.

Thank you.

DR. OSTROFF: Questions?

DR. SHOPE: Bob Shope.

Are there chronic carriers? And is it possible that in some of these establishments there are permanent staff who may be carriers and starting when new recruits come in, starting an epidemic?

DR. ANDERSON: You can certainly have prolonged excretion of adenovirus, months for some of the adenovirus serotypes, and I don't know for sure if that's actually been demonstrated with Ad-4 and 7. Certainly some of them can be.

You know, if you look at lymphocytes and some of the lymphoidal tissue, you may be able to find adeno for years, but I don't know if you can find it for Ad-4 and 7.

And I also don't know if that would likely

be important in transmitting in this setting. I don't know. I don't know the answer.

DR. OSTROFF: Dr. Haywood.

DR. HAYWOOD: Were the patients with tracheostomies and who died younger than the others?

DR. ANDERSON: In the pediatric chronic care facility, the higher rate of mortality and more severe disease was in younger children. I mean there are other factors that come into play in the outcome of death, and tracheostomy is just one of those. That's actually very important.

This data is consistent. I'm not even sure I'd call it suggestive. You have to be very careful in making that assumption, and you're absolutely right.

DR. DINIEGA: Larry, what do you make of the benzathine penicillin issue?

DR. ANDERSON: Well, in terms of adenovirus ARD I would be real surprised. I really don't know. I'm skeptical, but I don't know. I haven't seen the data, and I guess I could come up with some -- you know, maybe the bacterial infection predisposes to severe adenovirus disease or the other way around, but I'm skeptical, but I don't know.

DR. CAMPBELL: Doug Campbell.

What do you make of the seasonality of adenovirus? In some of these studies it looks like it's a year long phenomenon. In other studies it seems like it's just in the wintertime. What do you make of that?

I mean, it makes sense that it's a wintertime kind of phenomenon, but some of the data doesn't go along with that.

DR. ANDERSON: Well, I don't know why you have winter seasonality for anything. I can come up with some hypotheses, but influenza RSV, parainfluenza, I mean, they all have somewhat unique seasonality patterns. Why? We really don't have a clue.

I think the reason you're having year round disease is that you're having endemic transmission, mixing somehow of infected populations with susceptible populations or fomite transmission is another possibility.

So I think I've got a reason that I think is probably true for year round disease, but why you have wintertime disease I have no idea.

DR. LANDRIGAN: What happens in the Southern Hemisphere?

DR. ANDERSON: I don't know about

adenovirus, but I know for flu and RSV they have it in their wintertime, which would be our summertime in the temperate climates. When you get into the tropical climates, it's --

DR. LANDRIGAN: Year round?

DR. ANDERSON: Well, it varies. There's sometimes seasonality and sometimes there's not. It's hard to know what's going on.

DR. OSTROFF: Other questions?

(No response.)

DR. OSTROFF: I think we need a break. Everyone needs a caffeine jump, I think. Why don't we take a 15 minute break, and then we will have to come back to the subcommittee?

DR. HERBOLD: Steve, will we have a chance in our general discussion on the adenovirus issue and epidemiology?

DR. OSTROFF: Yes.

DR. ATKINS: And what is the plan with the subcommittees? Are we going to meet as subcommittees even though only one of the subcommittees has a question on the table so far?

DR. OSTROFF: What I thought we would do is go over kind of to divvy up the work for the questions we have coming tomorrow and discuss how we

want to do that and then let you know what we have as far as the background materials and everything for you.

DR. ATKINS: Okay.

DR. OSTROFF: And then if the subcommittees do want to break out, we can either do so here or do the other room or potentially wait until tomorrow.

DR. ATKINS: Very good.

(Whereupon, the foregoing matter went off the record at 3:45 p.m. and went back on the record at 4:12 p.m.)

DR. OSTROFF: I usually don't bang the gavel for the discussions.

I think, you know, we have until 4:45, and then we have to break for a few minutes and then have the tour, which I'm looking forward to. I thin it will be pretty interesting.

There are essentially two issues, I think, that at least I've identified over the course of the day to discuss. I think the primary one that we can discuss this afternoon is the adenovirus issue, and the second one is the presentation that was given this morning about the DMSS, the disease surveillance system.

I know that there were a lot of issues that arose about that particular system and how it's being utilized, you know, if there's time, and I think there are issues that relate to that particular system that aren't simply the reportable infectious diseases. There probably are issues for all of the subcommittees to think about discussing.

If there's time this afternoon we can address that. I suspect that we'll spend most of our time talking about the adenovirus though in this particular session.

So why don't we just go ahead and open up the discussion? I know that Dr. Berg in particular has spent some time looking at some of the issues related to adenovirus.

DR. BERG: I was looking at some of the other articles on the spread of respiratory diseases, not so much on adenovirus, and in fact, I don't really have much to say. There were some articles that I had wanted to dig out, and the one, you know, that I was talking to people about, a study that Jack Gwaltney did several years ago, and unfortunately I can't remember how it came out, but he inoculated volunteers with rhinovirus and then had them play poker at the height of their runny noses, and they tossed the chips

in, and then periodically they would collect the chips and take it into a separate room where another group of volunteers were who got these sticky chips to play with.

(Laughter.)

DR. BERG: My recollection is that, you know, the second group did not get infected, and this was an argument that hand transmission did not play much of a role, but I can't --

DR. OSTROFF: I would defer to Larry Anderson on that one.

DR. BERG: I can't remember. I may be 180 degrees out on that.

DR. ANDERSON: Gwaltney and Dick in Virginia and in Wisconsin have done studies, and they've looked at hand transmission versus droplet transmission, and I don't remember which group found it which way, but they basically have demonstrated that droplet transmission can occur. In fomite transmission, direct contact occurs such that you can do it when you put facials and you're not getting droplet, and you can do hand to hand transmission, fomite transmission.

And rhinovirus is like adenoids, a crystalline-like virus, non-enveloped. It's very

stable in the environment. So it's not surprising that fomite transmission would occur with rhinovirus. I think the question really was can you get droplet transmission in addition, and I think some of the studies suggest you can, and in some it's not quite so clear.

So fomite hand, direct contact, clearly for rhino and clearly for adeno, and for rhino the question is can you get aerosol droplet as well.

DR. SHOPE: Can you get fecal or oral with adeno?

DR. ANDERSON: Oh, yes. Now, whether or not you can get fecal or oral with Ad-4 and 7 I don't know, but certainly for some of the adenoviruses you can, and you can find both Ad-4 and 7 in fecal material. So I suspect it can occur.

My guess is it's not as efficient as respiratory transmission.

DR. HERBOLD: One of my questions was would it be possible to get some or some more simple two-by-two tables that looked at adenovirus epidemic rates by time on station, training day, part of the country, population density. You know, was it 2,000 or was it 15,000 on post?

And also look at some stratification of

those risk factors because we can go with what's been classically talked about, which is, you know, the head to toe and wash your hands and those types of things, but we haven't -- I don't feel comfortable that we've explored the epidemiology.

And it looks like with the surveillance program that I know that you all have had going for so long and the systematic collection of data by you all, but at the Navy Health Research Center, that we could slice and dice this and look at some two-by-two tables and see if there are some factors there that explain the seasonality and/or if there's a threshold of population density or if you look at recycles, you know, is there any association with how many are recycling and/or with activity in permanent party staff?

You know, you could go and look and see how many of these are in trainees. Like I know with the Air Force Project Gargle, you could look and see are they basic trainees or are they permanent staff at Lackland, and is there some predictor? Is the adenovirus activity brought in from outside or does it start mounting in the permanent party staff?

And then you know then, well, maybe it's a permanent party staff that you have to restrict.

DR. OSTROFF: Well, let me try to frame the discussion a little bit differently. Obviously this is an issue that I myself consider to be very important, as Jeff knows very well. I mean, I pushed pretty hard to get the fatalities reported in the MMWR, and I think as most of you are aware, that resulted in the article that showed up in the Wall Street Journal, which I think at least in part, although I don't know -- Ben, you may want to comment -- may have prompted or at least pushed forward the process of getting a new manufacturer for the vaccine.

I'm sure you all were working flat out on doing that anyway, but I guess the first question that I would pose to the preventive medicine representatives from each of the services is: how critical do you consider this to be an issue for you right now?

I mean, how does Health Affairs view the adenovirus issue right now? How is it viewed in the Army? How is it viewed in the Navy? How is it viewed in the Marines? How is it viewed in the Air Force?

And is the question that's posed to us important enough from the perspective of Health Affairs and the other agencies that they really want answers to some of these questions and will implement

the recommendations because it strikes me when I listen to the presentations that were given, that, I mean, there's a phenomenal amount of incredibly interesting information that's just sitting there. It's a treasure trove of information, and it's already there, and there are a phenomenal number of opportunities to do investigations to try to see and determine what works and what doesn't work and study it in some sort of a systematic fashion.

But that takes resources, and the question is: is this viewed as being important enough to Health Affairs and the services that they will either agree, number one, and, number two, resource those studies being done int the way that they need to be done to really develop answers that will allow us in more confident fashion to say you should do this versus this or something else?

DR. DINIEGA: I think the question was framed. The initiative to obtain another manufacturer has been going on for quite a while, and we're actually getting close to getting one, and the, I think, optimistic time frame of five to six years, maybe longer as you well know, depending on how things go with the FDA and if we fulfill all of the requirements.

If you think back to the HIV early days where all we had for preventive measures was education, I think we're sort of looking at what can we do in the meantime as an interim measure to try to minimize the attack rates because we really don't have anything. We don't have any therapy. We don't have any vaccine anymore.

But I think Jeff's slide -- I think it was Jeff -- that said don't detract from the efforts to get the vaccine is something we have to keep.

DR. OSTROFF: Oh, I couldn't agree with that more.

DR. DINIEGA: So I think the idea here is not to add more resources and the burden of resources, but to try to first look at what could possibly work on a non-vaccine method and then what things really sounds good, but it may need a little bit more work for us, you know.

DR. OSTROFF: Well, there's no question that getting the vaccine back is recommendation number one, two, three, four, and five, and everything else comes after that.

The question is: in that interval time period is this basically viewed as a distraction or is this viewed as a significant issue that needs to be

dealt with?

DR. DINIEGA: I think the view is that if there are measures that would help to reduce the rates of illness, and we need to do those now.

I do know for the Army, you know, the space issue that Jeff's talking about, the 72 square feet, the 72 square feet per soldier or per recruit, has come under attack on several occasions already. They've been asked to ease up on that because of space and money restraints.

DR. BERG: As I read the charge, it's a little broader than just adenovirus. It says, "Transmission of adenoviral and other acute respiratory disease causing agents in the Recruit Training Center," and it's almost as if, one, what can we do until we finally get the vaccine and, two, adenovirus isn't the only agent that ties up recruits. Are there more general things that have a more general effect?

And they ask us for, you know, recommendations, including recommendations for them to go out and test things.

DR. DINIEGA: Well, we wanted to have the categories of things that probably have some scientific backing, those that didn't and probably

needed to be tested more, and those that really needed a lot of work.

So we sort of have different categories of measures that could be implemented.

DR. OSTROFF: Well, I guess what I'm saying is that I think that there are some issues that are at least to some degree relatively no brainers, like hand washing. I mean, it's hard to be against hand washing.

There are other issues that I think will require additional epidemiologic and laboratory studies to be able to evaluate whether or not they really work or they don't work, and that takes time and resources.

And so if the Board makes a recommendation that certain issues that we don't feel confident enough or we don't feel that the data are necessarily clear enough to make a clear-cut recommendation that you ought to do this or this or this, that deserve further studies, do you think that there would be support for something like that?

DR. DINIEGA: I think that I would encourage the Board to make those recommendations, and then it would have to be looked at and the request go in for resources, and then it's going to have to fall

out with whatever parties that the department and services feel need to be done.

DR. OSTROFF: One other thing is that I don't feel that I have a sufficient knowledge base of exactly what type of studies are currently going on. I know, for instance, where Megan is doing something related to Great Lakes and this operation hand washing or whatever it's called. There must be some epidemiologic study that's buried somewhere in there unless it's simply an intervention.

Are there currently studies that are going on amongst the services other than the basic data collection?

COL. GUNZENHAUSER: Not in the Army.

DR. HERBOLD: Just an observation. What I see, again, I see a wealth of data, and you have to correct me if I'm wrong. There's variability between services. We have some historic data on the Air Force and the Coast Guard not having a recognized problem without vaccinating.

We see variability between Army training posts, and we can link the cases with the demographics of them, and I don't know if we know what point in training they were there, but I guess my question, my informal question is have we done the descriptive

epidemiology with the data set that we have, and could you share it with us?

DR. DINIEGA: I think what you saw was the ARD rates from ARD surveillance, which I think several of the speakers have said they don't routinely gather demographics, but they do the rates.

What the Board has not heard is the numerous formal outbreak investigations that have gone on and a summary of those findings. The Board in the past has heard those, but this Board has not heard those.

DR. HERBOLD: For example, on a different respiratory disease I remember at Lackland, again, I think it was in the face of an influenza outbreak. The issue, again, was could the trainees carry Kleenex in formation. So it's another anecdotal example of the wet sink issue.

You know, TIs didn't want them to have Kleenex in formation, and at that time the Epi Division was just looking at trying to reduce respiratory spread with sneezes and all that stuff, but you weren't allowed to cover your face and/or to use disposables because, you know, you weren't allowed to have Kleenex.

So I'm just wondering if maybe just a

review of the anecdotal information. You know, the hand washing thing, I know -- and, again, trying to get into the training schedule, changing the routine, the medics intervening, and you know, what the trainers do, and for certainly trying to get studies done is very, very difficult.

So I guess I'm asking have we mined the existing data enough to give us some clues as to what could be done, or are we going to be challenged on the 72 square foot?

If we reinforce that, do we know that that's of value? Do we know is triple bunking? You know, I'm trying to envision in my mind if you have head to toe bunking, but what does that mean at the double deck and the triple deck? And if someone is sneezing on the third bunk are they only sneezing into feet or are they sneezing into head? You know, what's the three dimensional picture of this?

DR. OSTROFF: Yeah.

COL. GARDNER: This is Colonel Gardner from Fort Bragg.

Let me just give you a little bit of perspective. You said hand washing is a no brainer, but it's a big issue. I mean it's a culture. This is a cultural issue. It's not really a preventive

medicine issue. Preventive medicine has the answers. The problem is breaking the culture.

The culture is health is never a first priority. There's always other things going on. There's never resources that anybody is willing to spend on health because they're spending it on everything else.

And basic training is to establish discipline, and part of discipline is you've got to have your bed made just right, and you've got to have your sinks clean and dry, and that means they'll only use one sink because then they'll only have to clean one sink, and it means you only get ten minutes to eat, and you don't have time to wash your hands before you go eat.

And this is a culture. It's not a preventive medicine problem. It's a training problem and a cultural problem.

The people that would be analyzing the data that you are seeing are the ones who are running from one thing to the next because the culture demands it, and in the operational environment they really actually do try to get database decisions, but what that means is you run out and you grab what you can find, and you put together preliminary results.

The decision is made, and then you're on to the next problem, and nobody ever has time to convert preliminary results into final results. And that's a culture that's difficult to deal with and difficult to change.

You know, my own work has been in heat stroke and exercise related deaths, and trying to change that culture where the focus is on retaining maximum fitness and athleticism in every soldier causes injury to at least 25 percent and sometimes 50 or 60 percent of every recruit, of all the recruits, and sometimes serious injury and death because of that focus.

And so you're really asking the wrong people to address the problem. The people that need to address the problem are those in charge of the culture, and they're too busy focused on other issues.

At Fort Bragg we had water that didn't meet EPA guidelines for eight years before anybody would put the resources into fixing it, and the only reason they did that was because EPA fined them several million dollars. You know, the only way you're going to get response is if OSHA comes in or someone comes in and institutes a multi-million dollar fine.

And then they'll say, "Okay. We'll spend a couple million to fix it, and then we'll negotiate the fine down." That's how it works.

So somehow you have to break that culture. We do a lot of -- from a health perspective we do a lot of stupid things like dry sinks and so on, and somehow we have to break that culture.

People here all know what the problem is and how to fix it, but you know, we should have a vaccine manufacturer 15 years ago, and we all know it, but nobody has been able to. We still haven't go tone.

DR. OSTROFF: Yeah, let me just say in response, thank you for your comments. I'm appreciative of the fact that basic training in and of its nature is a relatively unhygienic activity. There's little question about that.

And so, you know, instilling a culture of hand washing only can potentially go so far, although if the Marines can do it, I think probably anybody can do it.

CAPT. SCHOR: Because the Inspector General said to do it.

(Laughter.)

DR. HERBOLD: You can't do that with the

medical population.

DR. OSTROFF: Well, but you know, hey, in recruits.

Ken?

CAPT. SCHOR: Well, you know, this raises -- this is Captain Schor -- this raises the interesting issue of the Training and Education Command that owns the Marine Corps Recruit Depots and the basic school and Officer Candidate School for the Marine Corps is not exactly beating down my door with concerns about this issue.

However, there are concerns, probably more general concerns about acute respiratory disease because Marines out in Camp Pendleton, they had some fairly sick Marines with pneumonia and some other mixed causes last year.

So I think it's a more general issue amongst the leadership. It would be considered more broadly, and I just wonder if this might -- you know, I'm not sure if this is appropriate, but I just kind of throw it out on the table, is perhaps one action of the Board might be to frame some fairly simple and straightforward questions to the folks that own the accession pathway of the services to say, "How do you think about this? Is this an issue for you? Do you

perceive the respiratory disease is costing you money, is costing you training days, is causing you to have recidivism in your training?"

That's what really speaks to them, and then how would you consider ranking interventions? Is it the no cost/no time interventions versus the high cost/high time interventions, something like that? It might be an interesting approach.

DR. OSTROFF: Let me say one other things is that I posed the question to Colonel Staunton this morning and asked him whether or not adenovirus was an issue in British military recruits, and his response was not to his knowledge.

Now, I don't know how intensively anybody looks for it in British military recruits, and I would wonder if this is considered an issue in Canadian recruits.

LT. COL. FENSOM: We have never vaccinated for adenovirus in our recruits, and to my knowledge it hasn't been much of an issue, and I'm hypothesizing it may have something to do with the fact that we train in very small groups and we have a small recruiting pool.

But I would certainly go back to Ottawa and ask some questions about that.

DR. OSTROFF: Well, again, as I mentioned to him this morning, sometimes it's almost as important to look at why certain circumstances don't have problems as it is to look at why certain circumstances do. And obviously if this is something that seems to be uniquely American in comparison to other militaries, there must be something that we're doing that others aren't.

DR. GAYDOS: May I make a comment?

DR. OSTROFF: Yeah. Maybe they're just not looking. I don't know.

DR. GAYDOS: Joel Gaydos.

I've been following respiratory disease in the military for about 30 years, and adenovirus has been a problem in other countries. It's been reported in the Dutch military. It's been reported in the Indian military.

One of the reasons that we think we haven't seen more of a problem in other militaries is because of size of the other militaries and because size and conditions would allow them to cycle their training such that they would be able to train more in the summer months and not train in the colder winter months.

I think that it would be a good idea to

look at the whole gamut of febrile respiratory diseases for a number of reasons. We are having trouble now with influenza vaccine, and in 1976, we had a lot of very good vaccines, but we had to stop the flow of recruits into Fort Dix, New Jersey, and we had to do that because we just had so many cases of respiratory disease that we couldn't handle it.

And the reason was that we missed on the influenza vaccine that year, and something else happened that occasionally happens, and that's a non-force adenovirus outbreak, and we had a Type 11 outbreak up there that winter.

And so we do see Type 11. We do see Type 3 occasionally coming in.

Some of us are very concerned not only about the influenza vaccine, but we're also concerned about where we're going with meningococcal vaccine. Now, we are relying on a sole producer for meningococcal vaccine. We're moving to a new meningococcal vaccine. I'm not sure how things are going to stack up when we go to a new conjugate vaccine and whether we're going to see a quadravalent conjugate vaccine coming out there, where there is going to be some lapse.

I don't know how this is all going to be

handled. I don't know if anybody has ever thought about this, but I think we've had enough problems with vaccines that we have to expect that we're going to have trouble.

If you look at what data were presented today and if you read the literature, you will note that under -- we have this gap of about maybe 40 to 60 percent of acute respiratory disease being unaccounted for. We can account for somewhere around 40 to 60 percent as adenovirus.

It seems that when we get into a very hot outbreak, the percentage of isolates that are adenovirus approach 100 percent as we get more and more into a very hot outbreak.

But we run this maybe somewhere around 50 percent being adenovirus. We have data out there, a lot of things that have been done at the Naval Health Research Center, to indicate that we're probably seeing a lot of Chlamydia pneumoniae. We're probably seeing a lot of mycoplasma. We're probably seeing pertussis, and of course, we're seeing the other things, too, the peri-influenzas and other viruses.

But we have just been sailing along because of the vaccines that we got in the early '70s, the meningococcal vaccines, the adenovirus vaccines.

We've done reasonably well in predicting the influenzas, and so the military has really become very, very complacent.

But I think when we look at the situation, at the number of potential agents out there, when we look at the fact that our labs are not that well equipped probably even to quickly diagnose the Strep. pneumoniae outbreak as they used to be years ago that we are running a lot of risk with regard to basic training.

And if we have to mobilize our basic training centers, then I think we're in a position where we're going to see a lot of problems. And if you shut down basic training, particularly if hostilities are going on, that gets a lot of people very upset because that throws a monkey wrench into the whole personnel system that ends up supplying the people out there who are pulling the triggers and cocking the cannons.

So this is a potentially dangerous situation. I think we're dealing with a couple of generations of people now who aren't really sensitive to the problem, but I think it is a problem, and I think those who are at Great Lakes when they had the problems, those who were there when they had the

deaths, both the medical and the line people will tell you it's a problem.

I think those people at Lackland who are in the medical arena when they were overwhelmed will tell you it's a problem.

I can tell you the people at Jackson said it was a problem. They were very, very concerned about being overwhelmed in the medical arena.

So it is a problem, and I think that it has got to be approached with the whole idea of febrile respiratory disease.

When you look at all of the variables, Dr. Herbold, it's overwhelming. The facilities are different. Great Lakes is terrible. I mean it's a very old facility, and there's probably very little that they can do with that.

Lackland looks nice from the outside, but as Dana mentioned, you go in there and the classrooms, I mean, those folks are just shoulder to shoulder, and I can't understand it because we're not at war, and I think, you know, we're probably just cutting down on space to conserve heating and air conditioning costs.

If you look at some of the newer things, the things that Dr. Gunzenhauser mentioned with regard to what are called the starships, these things were

built according to state of the art heating, ventilating and air conditioning standards, which are not medical standards. They're comfort standards, but they were built to standards.

But there was a team from the Army Environmental Hygiene Agency, which is now the Center for Health Promotion and Preventive Medicine, that went down there and looked at those starships when that outbreak occurred, and what the found was that the original design standards meant absolutely nothing because they did not allow make-up air because to conserve heating costs. They were not maintaining those systems. They were not changing the filters, and of course, you had all of these variables.

And some of them actually brought in fans and created dead air spaces that wouldn't have existed. So you have all of those variables, the training situation, the sleep situation and all of the other things.

So it has been kind of overwhelming to try to sort all of those out. I think my estimation would be that we're going to be very lucky if we see a vaccine in eight years, and we will know more about that, I think, in the next few years as we get into looking at the cell lines and seed viruses and see

what the FDA is going to require with those.

But what we face right now is a situation where I think that the antivirals, which were mentioned today, are something that needs to be looked at because that may not be as costly or as far out a possibility.

But I think when we look at the barracks, if you put yourself in the position of someone who is in the medical department at an organization that's experiencing an outbreak and you go up and you tell them to do this A, B, or C or D, and they're going to come back at you and they're going to say, "Show me the data for the 72 square feet," and you can't do that, then you can't get something done.

And then if they do it and the rates continue to climb, then you use credibility, and it all gets back to what has been said here several times. The data don't exist there. There are not the data there that allow you with confidence to go forward.

And if the United States military all of a sudden got very, very rich and said, "We're going to build new barracks at all of these basic training centers," and called the Medical Department in and said, "Okay. You give us the health standards that

you want in there to control respiratory disease," I don't know where you folks would go to get that information.

And I think that a big part of that problem is that a lot of the basic studies have not been done. I think that Dr. Micheljohn and Dr. Couch and Dr. Channock and Frank Top and that group; I think when the vaccines came out 30 years ago, everybody thought it was a waste of money, and they stopped all of the studies.

So we don't have the data. We don't have anything on line for about the next eight years. Even if somebody came forward and said, "Okay. We'll do anything you tell us to do," what are you going to tell them because you're at risk of really losing credibility if you come out with some recommendation that's going to cost money or in somehow some way cause a major problem in the way they're training right now?

So it's a very, very difficult situation, but I think as a minimum the people I talk with are getting hit every day with the list of things that you've been presented on the slides up there such as UV lights and hand washing and wipes and all the other things.

And I think that as a very minimum if the people at the training centers were able to get a clear reading on those as far as what's in the literature and how well they're supported, that they would be better off than they are right now.

DR. BERG: I first started coming to the AFEB many years ago when guys like Ted Woodward and Bill Jordan and Bud Benenson, who was my MPH thesis advisor, were here, and one of the things I learned from them is that the AFEB works best when it gets specific questions.

And I'm a little confused now. What I'm hearing, on the one hand, is that there's a lot of data out there. If it were examined, this might lead to some answers.

I'm also hearing that the things that are probably the most likely to contribute, such as hand washing and tissues, are common sensical enough to be implemented, but it's the recruit training culture that is preventing them.

I'm beginning to feel that the only thing that's really going to work are one shot fixes like benzathine penicillin and vaccines.

So I think the question is: you know, what is the emphasis for this? And, you know, do you

want a recommendation from the Board that you should mount a definitive study to answer these things? Do you want a recommendation from the Board that the old barracks should be torn down?

You know, and I think this gets back to Steve's question about just how prepared is the military to answer these tough questions. You know, we've got a simple level of things that probably would help if they were implemented, but the Board can't do much about that.

And then it's a quantum leap up.

DR. OSTROFF: Yeah. I mean I've jokingly said to several people, you know, maybe we should suggest buying Holiday Inns and using them in place of barracks or something like that. It might be a cheaper solution.

COL. GUNZENHAUSER: I think that the one question that I would like to have an answer to is at least for the two things that we've identified as possibly beneficial an evaluation of what really is the level of scientific evidence that those are good, that is, hand washing and this space requirements issue.

I presume there's really quite -- I know that there's quite a bit of medical literature that I

know existed. I just haven't had the time to go look at, and I presume there's stuff in the AFEB archives from old work that was done that maybe could be looked at again, and the conclusion may be as Dr. Gaydos said there isn't enough.

So these are maybe a good idea, but we really can't recommend for or against. That would be useful to have that answered now, and that might be something that's easy to do.

But there's a couple other things that I think that are important. This could get driven pretty quickly. There's a couple of contingencies that are of concern.

I know that, for example, this outbreak at Fort Leonard Wood, the providers that were providing first line care were pretty indifferent. This is a common thing. You have an outbreak, and people just say, "Well, that's the way it is," and they just handle it.

But the command from the hospital was very concerned because they were shifting resources that took away from other important missions that were very expensive, and if I recall the peak epidemics that adenos had in the past, it's been a lot higher than 3.5 percent like we saw in this one outbreak.

So we potentially could see an outbreak at Fort Jackson this winter. If we get a surge of trainees, let's say, right now, let's say we have a bunch of recruits that sign up because of what's going on and we suddenly get a bolus, and it's November, and we have an outbreak at Fort Jackson where the rate goes up to four percent, and suddenly we've got 500 trainees that need care. It could drive interest tremendously.

So that's sort of a contingency in the background that has to be considered.

The other is the possibility that an outbreak could precipitate other associated illnesses, the interaction of various conditions we don't really understand very well, but perhaps the presence of adeno can bring in other diseases that are significant.

I think that's something that needs to be thought about. What's the potential for something bad happening? And should that drive some other questions?

Just two other points that I wanted to make. Something that we think is as simple as hand washing is really not easy to implement. I know in the Army where we have five basic training

installations, and they're in three different regions, I never really know whether I should be micro managing the local installation because like two of the installations don't have preventive medicine officers. So I have to figure out who's there, who's doing what, who's left.

Every July people leave. That's right when the summer surge comes. there's actually a lot of administrative oversight, at least from the Army's perspective, to assure that happens.

So even if we publish a policy and recommend it, without a lot of interaction I know that it wouldn't happen. So I wouldn't want to just say, oh, we know it makes sense intuitively and expect it to occur because I know it won't just because of the way things work.

DR. OSTROFF: You know, maybe I'm more optimistic. I mean, this isn't a policy that would be a service-wide policy. I mean you're talking about a unique setting, which is recruit training. There aren't that many recruit training facilities.

There are a total of what, nine for all of the services combined, approximately nine?

COL. GUNZENHAUSER: Nine, including the Coast Guard.

DR. OSTROFF: Yeah. You know, maybe one recommendation is that if there are specific recommendations regarding things like hand washing that in each of those facilities there is a designated official and probably somebody other than a preventive medicine type that's responsible for implementing that particular policy.

LT. COL. RIDDLE: But you've already got that out. I mean if you look at this Army policy from January of '00 --

DR. OSTROFF: It didn't work.

LT. COL. RIDDLE: -- it includes everything that we've discussed today.

DR. BERG: Well, why do you think the AFEB says every recruit has to wash their hands six times a day? The recruit commanders, the company commanders and DIs are going to say, "Yes, sir."

COL. GUNZENHAUSER: Well, I guess my position is I have a hard time advocating it when I don't really know what the level of evidence is for or against it.

LT. COL. RIDDLE: But the same thing is have you gone to the ASBREM (phonetic) and DDR&E through Health Affairs? I mean it doesn't take a rocket scientist to do the literature search, and

there's not a lot out there.

Have you taken to the ASBREM the issue is we need to fund research in this arena to build a body of evidence, or is that what you want the Board to recommend to Health Affairs to do?

COL. GARDNER: If the Board doesn't recommend it, it will never happen.

DR. OSTROFF: No, I know, and the Board is going to recommend. Don't worry about that.

COL. GARDNER: Even if they recommend it, it will happen, but it will be slow.

LT. COL. RIDDLE: But Dr. Clinton can go to the ASBREM and ask for the allocation of resources without the Board's recommendation.

DR. OSTROFF: Let's take two more, and then we're going to have to break. So Dr. Landrigan and then Dana.

DR. LANDRIGAN: The first thing --

DR. OSTROFF: We'll talk more about this tomorrow.

DR. LANDRIGAN: I was thinking about what Dr. Herbold said about the surveillance data, and I think the surveillance data are very useful, but useful up until a point. They're useful because they certainly show that outbreaks are occurring. They

show that there's differences between bases.

As Joel said, there may be some very common sensical explanations for the differences between the bases, but as so often is the case, surveillance data are just not fine grained enough to give us etiologic information. They don't capture the kind of highly detailed individual information that you might get through a case control study.

So, frankly, I would recommend against putting a lot of effort into mining the data. I know it's always fun to think about how you would mine them, but usually it comes out dry. That's just my opinion, but take it for what it's worth.

With regard to what we as the AFEB ought to be doing, I think probably our responsibility is to come out with a very short list, two or three recommendations, and if good data -- if Joel, with all of his historical knowledge, is correct that even reaching back 30 years that good data on whether or not to wash your hands, whether or not to use a Kleenex, if those data are lacking, we know that those data will not be generated in less than two or three years. I mean, those kinds of studies just take time to do, but not as long as it takes to get a new vaccine through the Food and Drug Administration, but

still they're time consuming.

So is there any way we can shortcut the approach? And it seems to me that there probably is, and it's what you guys in the health care policy arena do, and that is either use ourselves, a subset of us, or a group of consultants whom we bring in and go through a little Delphi process and basically say that this distinguished group of gray haired people have come up with the following series of three recommendations.

And we pay very careful heed to what we've heard from the two colonels about the difficulty of putting this stuff into practice and give careful thought to how do we work the politics.

Do we go to Admiral Clinton? We've got the Marine Corps as a model. At least one service seems to be able to make these approaches work. How do we duplicate that model?

But I think that's the essence of it.

COL. BRADSHAW: This is Dana Bradshaw again.

Following up maybe on what Colonel Riddle was mentioning, maybe there's a few key questions, and hand washing could certainly be one of them, that we could just do the systematic evidence reviews on and

then get an evidence based approach to a few things that look promising or that we think that's there, if that, indeed, needs to be clarified.

I think we've had some things presented that suggested it, but I know at least Dr. Gunzenhauser may not be convinced yet, but I mean, if we need to, we should do that, and we can do that, I think if we put the resources behind it, but it's relatively low hanging fruit I would think.

The other thing is that I know Dr. Herbold and some others mentioned that they would like to see some of the outbreak investigations and two-by-two tables and odds ratios et cetera, and I guess the most recent one, given what we've had, is the one that Jim Neville has done down at Lackland.

And I can make that available. I actually have it here on my laptop, but I don't see that there should be any problem for anybody that's interested in looking through that.

For instance, he looked at a questionnaire for risk factors, and I know gender was one of the things that was questioned, but they show that male gender, the odds ratio is 1.33 of having increased likelihood of having respiratory symptoms during training. That may relate to the fact that males in

other studies have been shown not to wash their hands as frequently in other settings.

(Laughter.)

COL. BRADSHAW: But there actually was two on washing hands rarely or never after sneezing, and that had an odds ratio of 1.4, and that was significant also with a confidence interval; washing hands rarely/never after coughing; and then a high perceived level of stress.

There were some other things about, you know, certain blocks in the training group or dormitories that were more likely than others, which you might expect.

Interesting enough, even though males were more likely to have respiratory symptoms, female were more likely to be hospitalized, but that may fit with other health utilization things that we know of with women.

There were also some issues about some other factors, but it's fairly lengthy, as you might expect, and they looked at a lot of different things. So if you'd like to kind of go foraging for data, you're probably welcome to do that.

LT. COL. RIDDLE: You have a full report outside of the appendices. They're in your background

material, and I've got the full one from Jim and Roger's thesis, too.

DR. OSTROFF: We'd better go on a tour, five o'clock.

Adjourned.

(Whereupon, at 5:01 p.m., the meeting was adjourned.)

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